POLICY AND PROCEDURE

POLICY NAME: Transplant Service Authorization	**POLICY ID:** CC.UM.18
BUSINESS UNIT: Please refer to system of record – Archer	**FUNCTIONAL AREA:** Utilization Management
EFFECTIVE DATE: 03/01/2006	**PRODUCTS:** Marketplace, Medicaid, Medicare
REVIEWED/REVISED DATE: 02/15; 08/15; 12/15; 09/16; 12/16; 02/17; 09/17; 04/2018; 06/19; 10/19; 02/20; 03/21; 05/21; 08/22; 12/22	
REGULATOR MOST RECENT APPROVAL DATE: N/A	

POLICY STATEMENT:
This policy outlines the process for transplant services.

PURPOSE:
To provide and facilitate medically appropriate transplant services.

SCOPE:
This policy applies to Population Health and Clinical Operations and Medical Affairs

DEFINITIONS:
Medical Necessity: Covered services that are prescribed based on generally accepted medical practices in light of conditions at the time of treatment. Medically Necessary services are: appropriate and consistent with the diagnosis of the treating provider and the omission of such could adversely affect the member's medical condition; compatible with the standards of acceptable medical practice in the community; provided in a safe, appropriate, cost-effective setting given the nature of the diagnosis and severity of the symptoms; not provided solely for the convenience of the member, the physician, or the facility providing the care; those for which there are no other effective and more conservative or substantially less costly treatment, service or setting available: any request for care or treatment with respect to which the application of the time periods for making non-urgent care determinations:

Urgent Pre-service Request: Any request for care or treatment with respect to which the application of the time periods for making non-urgent care determinations:

- Could seriously jeopardize the life or health of the member or the member's ability to regain maximum function, based on a prudent layperson's judgment, or jeopardize safety of the member or others due to the member's psychological state, **or**
- In the opinion of a practitioner with knowledge of the member's medical or behavioral health condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request.

POLICY:
All transplant services require both a medical necessity review and determination and coordination of financial reimbursement.

The processing of all transplant requests is the responsibility of the Centralized Transplant Unit (CTU). Should a request for transplant services be received by the Plan, the Plan should notify the CTU by forwarding any documentation to the CTU the health plan designated fax number on the plan-specific prior authorization form. Phone inquiries regarding transplant services should be transferred to the CTU at 866-447-8773.

The Corporate Medical Directors, under the supervision of the Senior Vice President, Deputy Chief Medical Officer of Medical Affairs, are responsible for Level II review determinations for requests for transplant services. All determinations, including denial notifications, must comply with Federal/State regulations, external regulatory bodies (i.e., NCQA), and Plan Utilization Management and Care Coordination policies.

PROCEDURE:
NOTE: State/Plan exceptions are noted in attached addendum.

The CTU reviews requests for solid organ and stem cell transplants. All other requests including, but not limited to, for corneal transplant, pancreatic islet cell auto-transplant after pancreatectomy, or parathyroid auto-transplant after thyroidectomy are referred for health plan medical necessity review and determination.

The CTU approves one (1) visit for HLA Typing/Stem Cell Collection/Donor Search and Transplant Consultation at a participating (PAR) facility without medical necessity review and determination. All other transplant related requests require medical necessity review by the CTU.

A Transplant Evaluation and Listing at a PAR facility can be approved at Level I if all necessary documentation is obtained **AND** it meets all aspects of the pertinent Clinical Policy or appropriate medical necessity criteria. For any transplant evaluation or listing request that does not have all the required clinical documentation, does not meet all aspects of the pertinent Clinical Policy, or appropriate medical necessity criteria after Level I review, a Level II Corporate Medical Director review.

Facility determinations for all transplant evaluation and listing requests from non-participating (NON-PAR) facilities, or from facilities with transplant programs that do not meet CMS/COE approval requirements, must be made by the Plan Medical Director, regardless of the outcome of the CTU medical necessity review process. The Plan Medical Director is **not responsible** for medical necessity review and determination of transplant services.

If the CTU determines that the transplant request is medically necessary, the case is referred to the Plan Medical Director for review and determination of NON PAR facility use, CMS/COE exemption, or redirection to an appropriate alternative facility.

The transplant review process begins when a request is received by the CTU. The transplant review process is complete when written notification of a determination for the request is sent to the member and requesting facility per the Plan specific UM.05 – *Timeliness of UM Decisions & Notifications*. Approvals are finalized by the CTU Clinical Nurse Coordinator, Corporate Medical Director, or Plan Medical Director. All adverse determinations are finalized by the Plan Medical Director. All steps within the transplant authorization process must be documented within the applicable clinical documentation system.

I. Pre-Determination

A. The request for transplant services is received at the CTU.

B. Upon receipt of the review request, the CTU Non-clinical Program Coordinator confirms the following:

- Member eligibility
- Other primary insurance coverage
- Valid Facility National Provider Identification (NPI) and Tax Identification Number (TIN)

C. CTU Program Coordinator enters a referral into the clinical documentation system and tasks the referral to the CTU Clinical Nurse Coordinator.

D. CTU Clinical Nurse Coordinator validates member benefits for transplant type and identifies sources for coordination of benefits (COB).

- If other coverage is identified, that coverage is considered primary for Medicaid members. Refer to UM.01.05 – Coordination of Benefits/Subrogation.

E. CTU Clinical Nurse Coordinator reviews all information submitted according to work process UM.18.06 - Required Clinical Documentation - Transplant Service Authorization.

F. CTU Clinical Nurse Coordinator confirms the status of the requested facility as either PAR or NON-PAR:

- Facility is considered PAR if there is a proprietary agreement with a Centene Health Plan, regardless of product (Marketplace, Medicare, Medicaid)
- Facility is considered NON-PAR if there is not a proprietary agreement with a Centene Health Plan, or the Agreement excludes transplant services

II. Medical Necessity Determination

A. **Level I Review**:

CTU Clinical Nurse Coordinator reviews all relevant clinical documentation according to the pertinent Clinical Policy or appropriate medical necessity criteria.

B. **Level II Corporate MD Review**

For any Transplant Evaluation or Listing that does not have all required clinical documentation or does not meet all aspects of the pertinent Clinical Policy or appropriate medical necessity criteria, or is for a NON-PAR,NON-CMS certified facility, a Level II MD Advisor Review is required. The CTU Clinical Nurse Coordinator submits the request and a summary of the documented clinical information to the Level II Corporate MD for medical necessity review and determination in compliance with the timeframes outlined in the Plan UM.05 - Timeliness of UM Decisions & Notifications. **For Medicare requests,** reference MCARE.UM.08 - Part C Organization Determinations.

C. If approved, transplant evaluations are valid for **six (6) months** and Transplant listings are valid for **twelve (12) months** from the date of approval.

D. The Clinical Nurse Coordinator notifies the requesting provider and member of the decision in the timeframe and method outlined in the Plan specific UM.05 - Timeliness of UM Decisions & Notifications. For Medicare notifications, reference MCARE.UM.08 - Part C Organization.

E. If the Level II Corporate MD recommends that the request be denied, an Advisor review is created by the CTU within the clinical documentation system and forwarded to the Plan Medical Director (PMD) for final determination.

F. If the PMD concurs with the denial:

- The CTU Clinical Nurse Coordinator verbally notifies the requesting provider of the denial, and next steps in the process as outlined in the Plan UM.05 - Timeliness of UM Decisions & Notifications and UM.07 – Adverse Determination (Denial) Notices. **For Medicare requests,** reference MCARE.UM.08 - Part C Organization Determinations.
- The CTU Clinical Nurse Coordinator creates a UM Notification Task for the Plan to complete an adverse determination letter per the Plan process.
- The Plan designee is responsible for issuing the adverse determination letter as outlined in UM.07 – Adverse Determination (Denial) Notices. For Medicare requests, reference MCARE.UM.08 - Part C Organization Determinations.

III. Facility Determination and Financial Arrangements

A. All Transplant evaluation and listing requests from NON-PAR facilities or facilities that do not meet CMS certification must be referred for a Level II Plan MD review, regardless of the outcome of the CTU medical necessity review process.

B. The CTU Clinical Nurse Coordinator works with the Plan, to coordinate contract negotiations for payment of transplant services.

C. Procedure must be performed as follows:

- **Marketplace/Commercial Solid Organ Transplants**:
  All programs must be approved by the Centers for Medicare and Medicaid Services (CMS) in addition to participating in the Celtic Transplant Health Solutions Network ("Celtic") or transplant vendor network ("Vendor") as a Center of Excellence (COE) for the specific transplant type requested (including organ, and adult vs. pediatric). Centene contracts with National Transplant Networks to access facilities within those networks for Marketplace/Commercial lines of business. These networks develop their own criteria for evaluating transplant programs and refer to these programs as Transplant Centers of Excellence.
- **Medicare and Medicaid Solid Organ Transplants.**
  All programs must be CMS certified for the specific transplant type requested (including organ, and adult vs. pediatric). CMS does not designate facilities as Centers of Excellence, but instead requires transplant facilities to meet specific Conditions of Participation (CoP) for organ transplant programs. For the Medicaid line of business, all transplant facilities must be enrolled in the state's Medicaid program.
- **Medicare, Medicaid and Marketplace Stem Cell Transplants**
  All programs that perform allogeneic SCT & autologous SCT unrelated stem cell transplants must be certified by the National Marrow Donor Program (NMDP), and COE approved for Marketplace (including adult vs. pediatric). Additionally, all programs must be accredited by the Foundation for the Accreditation of Cellular Therapy (FACT).

  The requirement for transplants to be performed at a CMS certified program or COE may be superseded by state law or regulation.

  If a Provider has a proprietary agreement (PAR facility) with a Centene Health Plan and it does not exclude Transplant, regardless of product, it governs which contract applies.

  - The Agreement must be submitted to PartnerRe for approval in order to maximize reinsurance. PartnerRe is Centene's Reinsurance vendor. As part of the Reinsurance Agreement, the CTU Clinical Nurse Coordinator must submit all proprietary contracts to PartnerRe for review and approval prior to utilizing the contract for transplant services. Once approved by PartnerRe, the contract does not need to be re-submitted unless the terms of the Agreement change.

D. If a provider has a proprietary agreement (PAR) facility, but the Agreement excludes transplant reimbursement:

- Validate Celtic National Contact agreements for participation in COE network.

- If no Agreement Exists:
    - Initiate SCA with Plan.
    - Refer to Transplant Health Solutions for SCA contracting support if needed.
- If unable to negotiate an SCA:
    - Refer to National Transplant Networks (Optum, Interlink, etc.)

E. If a Provider does not have an Agreement, or if the Proprietary Agreement excludes transplant reimbursement, they are considered a non-participating (NON-PAR) Provider.

- CTU Clinical Nurse Coordinator refers to the Plan Medical Director for Non-PAR facility determination or redirection to an alternative PAR facility. **This is not a review for medical necessity**, but for appropriateness of NON PAR facility use or redirection.
- CTU Clinical Nurse Coordinator includes turn-around-time (TAT) requirements and medical records for Plan MD review.
- CTU Clinical Nurse Coordinator notifies Corporate MD Level II Advisor of clinical case in the event the Plan Medical Director wants to consult on the member's clinical appropriateness for NON-PAR facility use or redirection to a PAR facility.
- Plan Medical Director makes approval/denial decision for NON-PAR use.
- Plan Medical Director sends facility determination back to the CTU Clinical Nurse Coordinator:
    - If approved for NON PAR use, CTU nurse communicates with the Celtic Transplant contacting team or Plan Contracting Department as appropriate, for negotiation of a single case agreement
    - The CTU does not negotiate contracts; but does initiate and facilitate the process between the Plan, Reinsurer, Plan Contracting and National Contracting (if required)

F. Is a Single Case Agreement (SCA) required?

- **Medicaid Product**
    1. The Celtic contracting team or the Plan Contracting Department (as applicable) attempts to negotiate an SCA at ≤ 150% of the State Medicaid fee schedule with the facility.
    2. If facility agrees to a rate of ≤ 150%, the case is deemed approved and submission to reinsurance vendor is not required.
    3. If facility disagrees, and the facility is demanding a rate that is greater than 150% of Medicaid, Celtic Contracting works with Plan to evaluate if the contract Agreements available through one of the Vendors provides better terms at the facility. If the Celtic contracting team has negotiated the SCA, an individual reviews the networks' rates to see if there are better Vendor terms available. If not, submit to the CTU nurse for submission to reinsurer.
        i. If yes, contract is placed with the Celtic transplant network or the Vendor
        ii. If no, the Celtic Transplant team or Plan Contracting executes an SCA utilizing Corporate National Contracting recommendations for support (CTU facilitates)
            a. Once SCA draft contract is complete, CTU submits draft to Reinsurance vendor for review and approval. CTU forwards a copy to Celtic Transplant Contracting if SCA is negotiated by the Plan.
            b. The contract remains unsigned (non-executed) by both parties (facility and Celtic or Plan Contracting) until after review by the corporate reinsurer and National Contracting. This step is **extremely important** to ensure maximum reinsurance reimbursement and optimal facility rates.
            c. Once SCA is returned from Reinsurer (with contract approval or recommendations), CTU communicates back to the Plan Contracting Department and/or Celtic National Contracting. This step may involve some back/forth between CTU, the Plan and Corporate Contracting until finalized.
            d. Once contract is finalized, Celtic or Plan Contracting and the rendering facility signs the Agreement.

e. Plan Contracting or Celtic transplant contracting team returns the signed Agreement to CTU Clinical Nurse Coordinator. CTU Clinical Nurse Coordinator retains contract in member's secure file.

f. CTU Program Coordinator documents contracting arrangements in Plan's claims payment system to ensure claim submissions are paid at the negotiated contract rates.

- **Medicare Product**

1. Celtic Transplant contracting or the Plan Contracting Department (as applicable) attempts to negotiate an SCA that is ≤ 120% of Medicare.
2. If facility agrees, the case is deemed approved and submission to reinsurer is not required.
3. If facility disagrees, and the facility is demanding a rate that is greater than 120% of Medicare, Celtic Transplant Contracting works with the Plan to evaluate if the contract Agreements available through a Vendor network provides better terms at the facility. If the Celtic Transplant contracting team has negotiated the SCA, they review the Vendors' rates to see if there are better terms available. If none of the Vendor contract rates are better, submit to the CTU nurse for submission to reinsurer.
    i. If yes, contract is placed with the Celtic transplant network or the Vendor network.
    ii. If no, the Celtic transplant contracting, or Plan Contracting executes a SCA utilizing Corporate National Contracting recommendations for support (CTU facilitates).
        a. Once SCA draft contract is complete, CTU submits draft to reinsurer for review and approval. CTU forwards a copy to Corporate National Contracting
        b. The contract remains unsigned (non-executed) by both parties (facility and Plan Contracting) until after review by the corporate reinsurer and National Contracting. This step is extremely important to ensure maximum reinsurance reimbursement and optimal facility rates.
        c. Once SCA is returned from Reinsurer (with contract approval or recommendations), CTU communicates back to Celtic transplant contracting or Plan Contracting Department. This step may involve some back/forth between CTU, the Plan and Corporate Contracting until finalized.
        d. Once contract is finalized, Celtic transplant contracting or Plan Contracting, and the rendering facility signs the Agreement.
        e. Celtic transplant contracting or Plan Contracting returns the signed Agreement to CTU Clinical Nurse Coordinator. CTU Clinical Nurse Coordinator retains contract in member's secure file.
        f. CTU Program Coordinator documents contracting arrangements in the Plan's claims payment system to ensure claim submissions are paid at the negotiated contract rates.

- **Marketplace Commercial**

1. Refer to Celtic Transplant Network or Vendor Transplant COE Network, unless Plan has different contacting arrangements (See Addendum).
2. Celtic transplant contracting works with Plan to confirm all applicable contract terms have been evaluated.
3. Vendor Agreements do not require signature or additional Reinsurance review.
4. The CTU Clinical Nurse Coordinator CTU retains vendor network payment arrangements in member's secure file.
    i. CTU Program Coordinator documents contracting arrangements in Plan's claims payment system to ensure claim submissions are paid at the negotiated contract rates.

7. If a financial agreement cannot be reached, or if a facility is denied for any other reason, it is the responsibility of the CTU Clinical Nurse Coordinator to assist the Plan to work with the requesting provider to coordinate services at an approved facility.
8. Facility denial notifications follows the procedures outlined in the Plan UM.07 Adverse Determination (Denial) Letters policy. For Medicare requests, reference *MCARE.UM.08 Part C Organization Determinations*.
9. The Plan has final responsibility and approval for determining the route of best financial interest.

IV. Post-Transplant Service Approval

All approved transplant candidates must be case managed from approval to procedure, at a moderate to high risk level unless member becomes ineligible for care management.

A. The CTU Clinical Nurse Coordinator makes a referral to Care Management at the time the Evaluation authorization is approved.

B. CTU Clinical Nurse Coordinator initiates the referral through the clinical documentation system.

C. All Transplant Evaluations are valid for **six (6) months** and Transplant authorizations are valid for **twelve (12) months** from the date of approval.

D. Annual extensions of transplant service authorizations require submission of updated clinical information for determination of continued medical necessity by the Corporate Level II MD Advisor.

- The CTU is responsible for verifying benefits and eligibility as described in the 'Pre-Determination' section of this policy.
- The CTU is responsible for providing updates to the Reinsurer, as appropriate or requested.
- The CTU initial approval letter submitted to the requesting facility includes the length of the approval (period of 1 year) as well as the following statement "Failure to submit the requested updated clinical within the requested timeframe will result in the loss of authorization for transplant services." Required updated clinical information is outlined in *UM.18.06 Transplant Service Authorization – Required Clinical Documentation* and listed in the attached document: "Transplant Services Request Required Clinical Information".
- Upon receipt of the clinical requesting transplant services extensions, a referral must be placed into the authorization system within the timeframe designated for each state.

E. Each individual Plan is responsible for entry of the inpatient authorization upon notification of the member's admission.

F. The Plan reviews any request for transplant service(s) performed without prior authorization in accordance with the Plan's retrospective review policy. If the Plan agrees to a retrospective review, the medical necessity review is performed by the CTU.

V. Multiple Listing

Protocol does not allow for authorizations for transplant services at multiple facilities for a single member, or requests for additional evaluations after transplant listing or transplant evaluation approval has already been rendered, except under the following:

- Member has an episode of illness that has changed their transplant status and due to the declining condition of the member; they are admitted to a geographically closer facility and are not stable for transfer to the previously approved facility.

VI. Reporting

The CTU submits a health plan specific log including all pending and recently processed transplant requests to the Plan on a monthly basis.

REFERENCES:
NCQA Health Plan Standards & Guidelines
UM.01 - Utilization Management Program Description
UM.01.05 - Coordination of Benefits/Subrogation
UM.02 - Clinical Decision Criteria & Application
UM.04 - Appropriate UM Professionals
UM.05 - Timeliness of UM Decisions & Notifications
UM.06 - Clinical Information
UM.07 - Adverse Determination (Denial) Letters
UM.18.06 - Transplant Service Authorization-Required Clinical Documentation
MCARE.UM.08 - Part C Organization Determinations

ATTACHMENTS:
Transplant Plan Specific Addendum
Buckeye Health Plan of Ohio Addendum

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Annual Review	Removed revision history prior to 2015. Updated "Procedure" to include the following: The CTU does not review requests for corneal transplant, pancreatic islet cell auto-transplant after pancreatectomy, or parathyroid auto-transplant after thyroidectomy. Updated "C. Facility Determination and Financial Arrangements" to include verbiage for Medicaid solid organ transplants and stem cell transplants. Updated Transplant Plan Specific Addendum to add Nevada (Silver Summit Plan), and updated Magnolia Plan language to include only that the CTU manages all transplant request and approval letters must be sent to the provider, facility, member, and DOM. Updated Addendum to include language for NV and PA Plans.	02/2017
Annual Review	No substantive changes.	09/2017
Ad Hoc Review	Removed revision history prior to 2015, revised statement under (*C. 2. A.) Facility Determination and Financial Arrangements* to: "Medicare and Medicaid solid organ transplants: all programs must be CMS-approved, and additionally have either stand-alone UNOS or stand-alone CMS approval for the specific transplant type requested (including organ, and adult vs. pediatric), regardless of the Centene Reinsurer Transplant Network Center of Excellence (COE) approval status."	04/2018
Annual Review	Under **Procedure** removed age restrictions for requiring a level II review for transplant listings for patient 18 and younger. Revised Level II review requirements for clarity, *"approvals will be issued by the Clinical Transplant Coordinator" to "approvals will be finalized……"* Revised **Pre-Decision** language to remove individual product lines. Revised CTU referral to reflect the referral is 'tasked' to the Clinical Nurse Coordinator versus placed in a "Pend/Under Review" status. Revised **Facility Par Status** to the following language, "*Facility is PAR and has transplant contract reimbursement language; forward to reinsurer for review and approval of the contracted rates.* *Facility is NON-PAR or does not have transplant contract reimbursement language; either the case is referred to the reinsurer for contract initiation or the Plan may choose to initiate a contract arrangement. The CTU forwards the Plan contract negotiations to the reinsurer for review and approval of the contract language and rates prior to the execution of the contract."* Removed redundant language regarding contracts that are negotiate at or less than 100% of State Medicaid FFS as it exists under the **Financial Arrangements** section. Revised **Medical Necessity Determination** and removed language regarding clinical documentation requirements, policy requirements and medical necessity criteria as it appears in other areas of the policy. Revised **Facility Determinations and Financial Arrangements** Revised and removed any language	6/2019

	related to associated DRG and state reimbursement rate as the Reinsurer is notified of all contracts with the exception of those negotiated at or less than 100% of the state Medicaid fee schedule. Revised **Post-Transplant Service Approval** and removed language that CTU is responsible for ongoing monthly confirmation of coverage if member has other primary coverage. "*This is not a CTU responsibility once member has been referred to Care Management."* Revised the North Carolina section in ***Attachment A - Transplant Plan Specific Addendum***.	
Ad Hoc Review	Removed ***Attachment B*** – ***Transplant Workflow*** from policy as the workflow is inaccurate.	10/19
Ad Hoc Review	Updated **Attachment A - Transplant Plan Specific Addendum** by revising *California* section and added new section, **District of Columbia** to list. Removed revision history prior to 2017. No other changes.	02/20
Annual Review	Revised Policy Section to include "Corporate Medical Directors are responsible for Level II review determinations. Under Procedure changed "Pre-Decision to Pre-Determination; changed "Clinical Nurse Coordinator" to "Clinical Nurse Coordinator"; Removed transplant reimbursement language from Pre-Decision area and moved under "Facility Determination and Financial Arrangements." Revised "Facility and Financial Arrangements" to include specific language for Medicaid, Medicare and Marketplace contracting and Reinsurance review.	03/21
Ad Hoc Review	Updated the **Transplant Plan Specific Addendum** by adding section for ***Fidelis Care of NY.***	05/21
Annual Review	Several edits made to sections: • III.3. a. - Marketplace/Commercial Solid Organ Transplants • III.3.c. - Medicare, Medicaid and Marketplace stem cell transplants • III. 6. - Facility Determination and Financial Arrangements, Medicaid Product and Medicare Product	08/22
Ad Hoc Review	Added addendum for Buckeye Health Plan of Ohio.	12/22

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.