### OFFICE OF THE SECRETARY OF STATE

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#### **ARCHIVES DIVISION**

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# TEMPORARY ADMINISTRATIVE ORDER

INCLUDING STATEMENT OF NEED & JUSTIFICATION

**DMAP 2-2023** 

**CHAPTER 410** 

**OREGON HEALTH AUTHORITY** 

HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

**FILED** 

01/31/2023 10:32 AM ARCHIVES DIVISION SECRETARY OF STATE & LEGISLATIVE COUNSEL

 $FILING\ CAPTION:\ Remove\ Outdated\ Solid\ Organ\ Transplant\ Criteria,\ Place\ On\ Prioritized\ List\ Of\ Health\ Services$ 

Guideline Notes.

EFFECTIVE DATE: 02/01/2023 THROUGH 07/30/2023

AGENCY APPROVED DATE: 01/31/2023

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# NEED FOR THE RULE(S):

The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements. The old criteria are delaying services to members who are need of transplant services. The transplant criteria will be removed from rule and posted on the prioritized list of health services guideline notes.

# JUSTIFICATION OF TEMPORARY FILING:

- (1) Failure to adopt and amend these rules could negatively impact Medicaid members that need transplant services, the current rules are outdated and cause delays for the transplant hospital's when prior authorizing transplant services for Medicaid members. The Health Evidence Review Commission (HERC) is updating the Prioritize List of Health Services February 1, 2023, the next update is October 1, 2023.
- (2) If these rules are not updated, the impacts Medicaid members needing transplant services and Hospitals providing the services.
- (3) Failure to update the transplant criteria and policy will delay services to Medicaid member in need of transplant services.
- (4) Updating the transplant policy will allow transplant facilities to provide transplant services to Medicaid members in a timely manner with no interruption to care coordination.

## DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

Prioritized list of health services guideline notes updated by the Health Evidence Review Commission (HERC).

### **RULES:**

410-124-0000, 410-124-0003, 410-124-0005, 410-124-0010, 410-124-0020, 410-124-0040, 410-124-0060, 410-124-0063, 410-124-0065, 410-124-0070, 410-124-0080, 410-124-0090, 410-124-0100, 410-124-0105, 410-124-0120, 410-124-0140, 410-124-0160

AMEND: 410-124-0000

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

CHANGES TO RULE:

410-124-0000

Transplant Services ¶

- (1) The Division of Medical Assistance Programs Health Systems Division (Division) will make payment for prior authorized and emergency transplant services identified in these rules as covered for eligible clients receiving the OHP Plus benefit package and when the Division Medicaid clients defined in OAR 410-124-0010 that meet the transplant criteria describoutlined in OAR 410-124-0010 and 410-124-00600 through 410-124-0160 is met. All other Benefit Packages do not cover transplant and the Prioritized List of Health Services guideline notes.
- (2) The Division will only prior authorize and reimburse for transplants if: ¶
- (a) All Division criteria are met; and ¶
- (b) Both the transplant  $\frac{\text{center}}{\text{hospital}}$ 's and the specialist's evaluations recommend that the transplant be authorized; and  $\P$
- (c) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141- $\frac{0.052383}{0.0000}$ .
- (3) Simultaneous multiple organ transplants are covered only if specifically identified as paired on the same currently funded line on the Oregon Health Plan (OHP) Prioritized List of Health Services whether the transplants are for the same underlying disease or for unrelated, but concomitant, underlying diseases.¶
- (4) Not Covered Transplant Services: The following types of transplants are not-covered by the Division: ¶
- (a) Transplants which are considered experimental or investigational or which are performed on an experimental or investigational basis, as determined by the Division;¶
- (b) Transplant services which are contraindicated, as described in OAR 410-124-0060 through 410-124-0160;¶
- (c) Transplants which have not been prior authorized for payment by the Division or the client's managed health care plan;¶
- (d) Transplants which do not meet the guidelines for an emergency transplant in OAR 410-124-0040;¶
- (e) Transplants which are not described as covered in OAR 410-141-0480 and 410-141-0520.¶
- (5) Selection of Transplant Centers: Transplant services will be reimbursed only when provided in a transplant center that provides quality services, demonstrates good patient outcomes and compliance with all Division facility criteria. The transplant center must have provided transplant services for a period of at least two years and must have completed a minimum of 12 cases in the most recent year. The patient-and-graft-survival rates must be equal to or greater than the appropriate standard indicated in this rule. A transplant center which has had at least two years of experience in transplantation of any solid organ (heart, liver, lung, if the criteria in (2) above is met:¶ (a) Solid organ, heart, kidney, liver, lung, heart-lung, pancreas, kidney-pancreas), and which has met or exceeded the appropriate standards may be considered for reimbursement for the transplantation of other solid organs and/or autologous or allogeneic bone marrow transplantation:¶
- (a) An experienced and proficient transplant team and a well established transplant support infrastructure at the same physical location as the transplant service is required for transplant services rendered to Division clients. These transplant criteria are crucial to successful transplant outcome. Therefore, consortia will not be approved or contracted with for the provision of transplant services for Division clients. No Division transplant contract, prior approval or reimbursement will be made to consortia for transplant services where, as determined by the Division, there is no assurance that the individual facilities that make up the consortia independently meet Division criteria. The Division's transplant criteria must be met individually by a facility to demonstrate substantial experience with the procedure;¶
- (b) Once a transplant facility has been approved and contracted for Division transplant services, it is obliged to report immediately to the Division any events or changes that would affect its approved status. Specifically, a transplant facility is required to report, within a reasonable period of time, any significant decrease in its experience level or survival rates, the departure of key members of the transplant team or any other major changes that could affect the performance of transplants at the facility. Changes from the terms of approval may lead to prospective withdrawal of approval for Division coverage of transplants performed at the facility;¶ (c) Coordinated care organizations (CCOs) that contract with non-Division contracted facilities for small bowel;¶ (b) Bone marrow and peripheral stem cell:¶
- (c) Corneal transplants;¶
- (d) Simultaneous multiple organ transplants are covered only if specifically identified as paired on the same currently funded line on the Oregon Health Plan (OHP) Plus clients will develop and use appropriate transplant facility criteria to evaluate and monitor for quality services at the transplant facility;¶

- (d) Transplant centers which have less than two years' experience in solid organ transplant may be reimbursed, at the Division's discretion, for allogeneic or autologous bone marrow transplants upon completion of two years of experience in bone marrow transplantation with patient survival rates equal to or exceeding those defined in section (5) of this rule;¶
- (e) The Division will discontinue the contract with a transplant center when the graft and/or survival rates fall below the standards indicated in this rule for a period of two consecutive years.¶
- (6) Standards for Transplant Centers:¶
- (a) Heart, heart-lung and lung transplants:¶
- (A) Heart: One-year patient survival rate of at least 80%;¶
- (B) Heart-Lung: One-year patient survival rate of at least 65%;¶
- (C) Lung: One-year patient survival rate of at least 65% rioritized List of Health Services whether the transplants are for the same underlying disease or for unrelated, but concomitant, underlying diseases.¶
- (b4) Bone Marrow (autologous and allogeneic), peripheral stem cell (autologous and allogeneic) and cord blood (allogeneic) transplants: One-year patient survival rate of at least 50%;¶
- (c) Liver transplants: One year patient survival rate of at least 70% and one year graft survival rate of at least 60%:¶
- (d) Simultaneous pancreas-kidney and pancreas-after-kidney transplants: One year patient survival rate of at least 90% and one year graft survival rate of at least 60%;¶
- (e) Kidney transplants: One year patient survival rate of at least 92% and one year graft survival rate of at least 85%.¶
- (7) Selection of transplant centers by geographic location: If the services are available in the state of Oregon, reimbursement will not be made to out-of-state transplant centers. Out-of-state centers will be considered only if ¶
- (a) The type of transplant required is not available in the state of Oregon and/or the type of transplant (for example, liver transplant) is available in the state of Oregon but the Oregon transplant center does not provide that type of transplant for all clients or all covered diagnoses, (e.g., pediatric transplants); and ¶
- (b) An in-state transplant center requests the out-of-state transplant referral; and ¶
- (c) An in-state transplant facility recommends transplantation based on in-state facility and Division criteria; or (d) It would be cost effective Not Covered Transplant Services: The following types of transplants are not covered by the Division: ¶
- (a) Transplants which are considered experimental or investigational or which are performed on an experimental or investigational basis, as determined by the Division. For example, if the transplant service is covered by the client's benefit package and the client's primary insurer (i.e., Medicare) requires the use of an out-of-state transplant center; or¶
- (e) It is a contiguous, out-of-state transplant center that has a contract or special agreement for reimbursement with the Division.¶
- (8) Professional and other services will be covered according to administrative rules in the applicable provider guides.¶
- (9) Reimbursement for covered transplants and follow-up care for transplant services is as follows:¶
- (a) For transplants for fee-for-service clients:: ¶
- (b) Transplants which have not been prior authorized for payment by the Division or the client's Managed Care Entity (MCE): ¶
- (Ac) Transplant facility services by contract with the Division;¶
- (B) Professional services at the Division's maximum allowable rates.¶
- (b) For emergency services, when no special agreement has been established, the rate will be:¶
- (A) 75% of standard inpatient billed charge; and ¶
- (B) 50% of standard outpatient billed charge; ors which do not meet the guidelines for an emergency transplant in OAR 410-124-0040;¶
- (Cd) The payment rate set by the Medical Assistance program of the state in which the center is located, whichever is lower.¶
- (c) For clients enrolled in CCOs, reimbursement for transplant services will be by agreement between the CCO and the transplant center ransplants which are not described as covered in OAR 410-141-3820 and 410-141-3830.

ADOPT: 410-124-0003

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

### 410-124-0003

Transplant hospital requirements and reimbursement

Transplant hospitals: Transplant services will be reimbursed only when provided in a transplant hospital that meets the Division requirements. ¶

(1) Medicare certified transplant facility.¶

(2) Must be an enrolled provider with Oregon Health Authority, Health Systems Division outlined in OAR 410-120-1260.¶

(3)Selection of transplant hospitals by geographic location: If the services are available in the state of Oregon, reimbursement will not be made to out-of-state transplant hospitals.¶

(4) Out-of-state transplant hospitals will be considered only if:¶

(a) The type of transplant required is not available in the state of Oregon and/or the type of transplant (for example, liver transplant) is available in the state of Oregon but the Oregon transplant hospital does not provide that type of transplant for all clients or all covered diagnoses, (e.g., pediatric transplants); and \[ \begin{align\*} \]

(b) An in-state transplant hospital requests the out-of-state transplant referral; and ¶

(c) An in-state transplant facility recommends transplantation based on in-state facility and Division criteria; or¶ (d) It would be cost effective as determined by the Division. For example, if the transplant service is covered by the client's benefit package and the client's primary insurer (i.e., Medicare) requires the use of an out-of-state transplant hospital; or¶

(e) It is a contiguous, out-of-state transplant hospital that has a contract or special agreement for reimbursement with the Division.¶

(5) Professional and other services will be covered according to administrative rules in the applicable provider guides.¶

(6) Reimbursement for covered transplants and follow-up care for transplant services is as follows: ¶

(a) For transplants for fee-for-service clients:¶

(A) Transplant facility services - by contract with the Division;¶

(B) Professional services - at the Division's maximum allowable rates.¶

(b) For emergency services, when no special agreement has been established, the rate will be:¶

(A) 75% of standard inpatient billed charge; and ¶

(B) 50% of standard outpatient billed charge.¶

(c) For clients enrolled in Managed Care Entity (MCE), reimbursement for transplant services will be by agreement between the MCE and the transplant hospital.

Statutory/Other Authority: ORS 413.042

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

410-124-0005 Donor Services ¶

- (1) Living and cadaver donor search and procurement services are covered for covered transplants.¶
- (2) All living or cadaver donor services are payable under the recipient's Medicaid identification number and not under the donor.¶
- (3) Living donor services prior authorization requirements for fee-for-service and Primary Care Case Manager (PCCM) clients:¶
- (a) Bone marrow, stem cells and cord blood:¶
- (A) Screening of potential living related donors does not require prior authorization; ¶
- (B) Unrelated/voluntary donor search requires prior authorization;¶
- (C) Collection and testing of related cord blood requires prior authorization;¶
- (D) Donor search costs up to the maximum amount of \$15,000 are covered only if donor search is prior authorized;¶
- (E) Procurement requires prior authorization of the transplant.¶
- (b) Kidney alone no prior authorization required for testing of or procurement from living or cadaver donors;¶
- (c) Other solid organs testing and procurement are covered if transplant is prior authorized; ¶
- (d) Payment is limited to donor expenses incurred directly in connection with the transplant. Complications of the donor that are directly and immediately related or attributable to the donation procedure are covered.¶
- (4) Cadaver procurement services prior authorization requirements for fee-for-service and PCCM-clients:¶
- (a) Covered if transplant is prior authorized; ¶
- (b) Procurement charges are included in the Organ Procurement Organization (OPO) charges to the transplant facility;¶
- (c) Payable only to the transplant facility per contract.¶
- (5) For Fully Capitated Health Plan (FCHP Managed Care Entity (MCE) clients, contact the client's FCHP MCE for authorization requirements.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

410-124-0010

Eligibility for Transplant Services ¶

- (1) To be eligible for transplant services the client must be <u>enrolled</u> on the <u>BasicOregon</u> Health <u>Care PackagePlan Plus benefit package (BMH) described in OAR 410-120-1210 (4)(a)</u> at the time the transplant services are provided.¶
- (2) Clients covered under the following Benefit Packages do not have coverage for transplants:
- (a) Limited Benefit Package (LMH, LMM) coverage only for mental health, alcohol/drug, pharmacy, and medical transportation services OHP with Limited Drugs (BMM, BMD) coverage only for services covered by Medicare;¶
- (b) Qualified Medicare Beneficiary (MED) coverage only for services covered by Medicare;¶
- (c) Citizen/Alien-Waived Emergencyship Waived Medical (CAWEWM) Federal rule egulations exclude coverage of transplants, even if emergent.  $\P$
- (3) If an individual is not eligible for the Basic Oregon Health Care PPlan Plus benefit package at the time the transplant is performed, but is later made retroactively eligible for the Basic Oregon Health Care Package, the Division of Medical Assistance Programs Plan Plus benefit package, the Health Systems Division (Division) will apply the same criteria found in OAR 410-124-0020 through OAR 410-124-0160 in determining whether to cover the transplant and transplant-related services. Payment can only be made for services provided during the period of time the individual is eligible.¶
- (4) The Division prior authorization is valid for transplant services provided only while the client is enrolled under fee-for-service-or a Primary Care Case Manager. If a client moves from the fee-for-service arena to a Fully Capitated Health Plan (FCHPto a Managed Care Entity (MCE), any prior authorizations which had been approved by the Division are void and prior authorization must be obtained from the new FCHPMCE. If a client moves out of an FCHPMCE into another FCHPMCE, or into fee-for-service, any prior authorizations approved by the original FCHPMCE or Division are void, and prior authorization must again be obtained from the new FCHPMCE or the Division.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

### 410-124-0020

Prior Authorization for All Covered Transplants, Except Cornea and Kidney ¶

- (1) The following services require prior authorization: ¶
- (a) All non-emergency transplant services, except for kidney alone and cornea transplants which require prior authorization only if performed out-of-state;¶
- (b) Pre-transplant evaluations provided by the transplant center hospital (for covered transplants only).¶
- (2) The prior authorization request for all covered transplants is initiated by the client's in-state referring physician or the transplant physician. The initial request should contain all available information outlined in subsection (3) of this rule, below:¶
- (a) For fee-for-service clients, the request should be sent to the Division of Medical Assistance Programs (Division):¶
- (b) For clients enrolled in a coordinated care organization (CCO), r:¶
- (a) For fee-for-service clients, the ODHS/OHA Prior Authorization Requests for transplant services should be sent directly to the CCO.¶
- (3) A completed request for authorization must contain the following information. Failure to submit all the information will delay processing of the request. An optional form (DMAP 3084 Requesm MSC 3971, EDMS Coversheet form MSC 3970 and Document for Transplant or and Transplant Evaluation) is provided on the Transplant Services Web page at www.oregon.gov/OHA/healthplan/pages/transplant.aspx for provider convenience in submitting requests:¶
- (a) The name, age, Oregon Health ID number, and birth date of the client;¶
- (b) A description of the medical condition and full ICD-10-CM coding which necessitates a transplant;¶
- (c) The type of transplant proposed, with CPT code Request form OHP 3084 should be completed;¶
- (db) The results of a current HIV test, (completed within 6 mo For clienths of request for transplant authorization);¶
- (e) Any other evidence of contraindications for the type of transplant being considered (see contraindications under each transplaenrolled in a Managed Care Ent-itype);¶
- (f) The client's prognosis, with and without a transplant, including estimated life expectancy with and without the transplant;¶
- (g) Transplant treatment alternatives:¶
- (A) A history of other treatments which have been tried;¶
- (B) Treatments that have been considered and ruled out, including discussion of why they have been ruled out.¶ (h) An evaluation based upon a comprehensive examination completed by a board certified specialist in a field directly related to the condition of the client which necessitates the transplant (MCE) requests for transplant services should be sent directly to the MCE;¶
- (ic) If already done before requesting prior authorization, the results of any medical and/or social evaluation completed by a transplant centerhospital should be included in the prior authorization request. The completion of an evaluation by a transplant centerhospital before receiving prior authorization from the Division does not obligate the Division to reimburse that transplant centerhospital for the evaluation or for any other transplant services not prior authorized.¶
- (43) Prior authorization approval process and requirements:¶
- (a) For clients receiving services on a fee-for-service basis:¶
- (A) After receiving a completed request, the Division will notify the referring physician within two weeks if an evaluation at a transplant <u>centerhospital</u> is approved or denied;¶
- (B) A final determination for the actual transplant requires an evaluation by a selected transplant <del>center</del><u>hospital</u>, which will include:¶
- (i) A medical evaluation; ¶
- (ii) An estimate of the client's motivation and ability, both physical and psychological, to adhere to the post-transplant regimen;¶
- (iii) The transplant center hospital's assessment of the probability of a successful outcome, based on the type of transplant requested, the condition of the client, and the client's ability to adhere to the post-transplant regimen; and ¶
- (iv) A recommendation using both the transplant centerhospital's own criteria, and the Division's criteria.¶

- (b) For Oregon Health Plan (OHP) transplant eligible clients who are in an  $\frac{CCOMCE}{CCOMCE}$ : Refer to the  $\frac{CCOMCE}{CCOMCE}$  for approval process and requirements;¶
- (c) The prior authorization request will be approved if: ¶
- (A) All Division criteria are met; and ¶
- (B) Both the transplant  $\frac{\text{center}}{\text{hospital}}$ 's and the specialist's evaluations recommend that the transplant be authorized; and  $\P$
- (C) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services.¶
- (54) The referring physician, transplant <u>centerhospital</u>, and the client will be notified in writing by the Division or the <u>CCOMCE</u> of the prior authorization decision.
- (6) Prior authorization of a transplant does not guarantee reimbursement for the services of any provider if, at the time the transplant is performed, intercurrent events have caused the individual's medical condition to deteriorate to the point at which survival with or without transplant for a period of more than sixty days is unlikely.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

410-124-0040

Emergency Transplants ¶

- (1) An Emergency Transplant is one in which medical appropriateness requires that a covered transplant be performed less than five days after determination of the need for a transplant.¶
- (2) Emergency transplants are subject to post transplant review of the client's medical records by the Division of Medical Assistance Programs Health Systems Division (Division), or the Fully Capitated Health Plan (FCHP Managed Care Entity (MCE), to determine if the client and the transplant centerhospital met the criteria in these rules at the time of the transplant. Related charges, including transportation, physician's services, and donor charges will be covered if payment is approved. The Division will make payment as described in OAR 410-124-0000(9)3 for Division-covered transplants. FCHPsMCE will make payment as described in their contract.¶

  (3) Transplants are not covered byfor Citizen/Alien-Waived Emergencyship Waived Medical (CAWEWM) clients, even when emergent.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

#### **CHANGES TO RULE:**

#### 410-124-0060

Criteria and Contraindications for Heart Transplants

- (1) Prior authorization for a heart transplant will only be approved for a client in whom irreversible heart disease has advanced to the point where conventional therapy offers no prospect for prolonged survival, there is no reasonable alternative medical or surgical therapy and the client's five (5) year survival rate, subsequent to the transplant, is at least 20 percent as supported by medical literature.¶
- (2) A client considered for a heart transplant must have a poor prognosis (i.e., less than a 50% chance of survival for 18 months without a transplant) as a result of poor cardiac functional status or cardio/pulmonary functional status.¶
- (3) All alternative medically accepted treatments that have a one year survival rate comparable to that of heart transplantation must have been tried or considered.¶
- (4) Requests for transplant services for children suffering from early congenital heart disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve the outcome.¶
- (5) A client with one or more of the following contraindications is ineligible for heart transplant services: ¶
- (a) Untreatable systemic vasculitis;¶
- (b) Incurable malignancy;¶
- (c) Diabetes with end-organ damage;¶
- (d) Active infection which will interfere with the client's recovery: ¶
- (e) Refractory bone marrow insufficiency;¶
- (f) Irreversible renal disease;¶
- (g) Irreversible hepatic disease;¶
- (h) HIV positive test results.¶
- (6) The following may be considered contraindications to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe the following condition(s) may interfere significantly with the recovery process:¶
- (a) Hyperlipoproteinemia;¶
- (b) Curable malignancy;¶
- (c) Significant cerebrovascular or peripheral vascular disease;¶
- (d) Unresolved or continuing thromboembolic disease or pulmonary infarction;¶
- (e) Irreversible pulmonary hypertension;¶
- (f) Serious psychological disorders;¶
- (g) Drug or alcohol abuse.¶
- (7) The Division of Medical Assistance Programs (Division) will only prior authorize and reimburse for heart transplants if:¶
- (a) All Division criteria are met; and ¶
- (b) Both the transplant center's and the specialist's evaluations recommend that the transplant be authorized; and ¶
- (c) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141-0520.

Statutory/Other Authority: ORS 413.042

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

### 410-124-0063

Criteria and Contraindications for Heart-Lung Transplants

- (1) Prior authorization for a heart-lung transplant will only be approved for a client in whom irreversible cardio-pulmonary disease has advanced to the point where conventional therapy offers no prospect for prolonged survival, there is no reasonable alternative medical or surgical therapy and the client's five (5) year survival rate, subsequent to the transplant, is at least 20 percent as supported by medical literature.¶
- (2) A client considered for a heart-lung transplant must have cardio-pulmonary failure with a poor prognosis (i.e., less than a 50% chance of survival for 18 months without a transplant) as a result of poor cardiac functional status or cardio/pulmonary functional status.¶
- (3) All alternative medically accepted treatments that have a one year survival rate comparable to that of heart-lung transplantation must have been tried or considered.¶
- (4) Requests for transplant services for children suffering from early cardio-pulmonary disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve the outcome.¶
- (5) A client with one or more of the following contraindications is ineligible for heart-lung transplant services: (a) Untreatable systemic vasculitis; ¶
- (b) Incurable malignancy;¶
- (c) Diabetes with end-organ damage;¶
- (d) Active infection which will interfere with the client's recovery;¶
- (e) Refractory bone marrow insufficiency;¶
- (f) Irreversible renal disease;¶
- (g) Irreversible hepatic disease;¶
- (h) HIV positive test results.¶
- (6) The following may be considered contraindications to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe the following condition(s) may interfere significantly with the recovery process:¶
- (a) Hyperlipoproteinemia;¶
- (b) Curable malignancy;¶
- (c) Significant cerebrovascular or peripheral vascular disease;¶
- (d) Unresolved or continuing thromboembolic disease or pulmonary infarction;¶
- (e) Serious psychological disorders;¶
- (f) Drug or alcohol abuse.¶
- (7) The Division of Medical Assistance Programs (Division) will only prior authorize and reimburse for heart-lung transplants if:¶
- (a) All Division criteria are met; and ¶
- (b) Both the transplant center's and the specialist's evaluations recommend that the transplant be authorized; and ¶
- (c) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141-0520.

Statutory/Other Authority: ORS 413.042

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

### 410-124-0065

Criteria and Contraindications for Single Lung Transplants

- (1) Prior authorization for a single lung transplant will only be approved for a client in whom irreversible lung disease has advanced to the point where conventional therapy offers no prospect for prolonged survival, there is no reasonable alternative medical or surgical therapy and the client's five (5) year survival rate, subsequent to the transplant, is at least 20 percent as supported by medical literature.¶
- (2) The client must have a poor prognosis (i.e., less than a 50% chance of survival for 18 months without a transplant) as a result of poor pulmonary functional status.¶
- (3) All alternative medically accepted treatments that have a one year survival rate comparable to that of single lung transplantation must have been tried or considered.¶
- (4) Requests for transplant services for children suffering from early pulmonary disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve the outcome.¶
- (5) A client with one or more of the following contraindications is ineligible for single lung transplant services:¶
- (a) Untreatable systemic vasculitis;¶
- (b) Incurable malignancy;¶
- (c) Diabetes with end-organ damage;¶
- (d) Active infection which will interfere with the client's recovery:¶
- (e) Refractory bone marrow insufficiency;¶
- (f) Irreversible renal disease;¶
- (g) Irreversible hepatic disease;¶
- (h) HIV positive test results.¶
- (6) The following may be considered contraindications to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe the following condition(s) may interfere significantly with the recovery process:¶
- (a) Hyperlipoproteinemia;¶
- (b) Curable malignancy;¶
- (c) Significant cerebrovascular or peripheral vascular disease;¶
- (d) Unresolved continuing thromboembolic disease or pulmonary infarction;¶
- (e) Serious psychological disorders;¶
- (f) Drug or alcohol abuse.¶
- (7) The Division of Medical Assistance Programs (Division) will only prior authorize and reimburse for single lung transplants if:¶
- (a) All Division criteria are met; and¶
- (b) Both the transplant center's and the specialist's evaluations recommend that the transplant be authorized; and ¶
- (c) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141-0520.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

#### **CHANGES TO RULE:**

### 410-124-0070

Criteria and Contraindications for Bilateral Lung Transplants

- (1) Prior authorization for a bilateral lung transplant will only be approved for a client in whom irreversible lung disease has advanced to the point where conventional therapy offers no prospect for prolonged survival, there is no reasonable alternative medical or surgical therapy and the client's five (5) year survival rate, subsequent to the transplant, is at least 20 percent as supported by medical literature.¶
- (2) The client must have a poor prognosis (i.e., less than a 50% chance of survival for 18 months without a transplant) as a result of poor pulmonary functional status.¶
- (3) All alternative medically accepted treatments that have a one year survival rate comparable to that of bilateral lung transplantation must have been tried or considered.¶
- (4) Requests for transplant services for children suffering from early pulmonary disease may be approved before attempting alternative treatments if medical evidence suggests an early date of transplant is likely to improve the outcome.¶
- (5) A client with one or more of the following contraindications is ineligible for bilateral lung transplant services: (a) Untreatable systemic vasculitis; ¶
- (b) Incurable malignancy;¶
- (c) Diabetes with end-organ damage;¶
- (d) Active infection which will interfere with the client's recovery:¶
- (e) Refractory bone marrow insufficiency;¶
- (f) Irreversible renal disease;¶
- (g) Irreversible hepatic disease;¶
- (h) HIV positive test results.¶
- (6) The following may be considered contraindications to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe the following condition(s) may interfere significantly with the recovery process:¶
- (a) Hyperlipoproteinemia;¶
- (b) Curable malignancy;¶
- (c) Significant cerebrovascular or peripheral vascular disease;¶
- (d) Unresolved continuing thromboembolic disease or pulmonary infarction;¶
- (e) Serious psychological disorders;¶
- (f) Drug or alcohol abuse.¶
- (7) The Division of Medical Assistance Programs (Division) will only prior authorize and reimburse for bilateral lung transplants if:¶
- (a) All Division criteria are met; and¶
- (b) Both the transplant center's and the specialist's evaluations recommend that the transplant be authorized; and ¶
- (c) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141-0520.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

### **CHANGES TO RULE:**

#### 410-124-0080

Criteria and Contraindications for Autologous and Allogeneic Bone Marrow, Autologous and Allogeneic Peripheral Stem Cell and Allogeneic Cord Blood Transplants ¶

- (1) The following criteria will be used to evaluate the prior authorization request for all bone marrow and peripheral stem cell transplants:¶
- (a) Transplantation must be the most effective medical treatment, when compared to other alternatives, in prolonging life expectancy to a reasonable degree;¶
- (b) The client must have a maximum probability of a successful clinical outcome and the expectation of not less than a 20 percent five (5) year survival rate, subsequent to the transplant, as supported by medical literature considering each of the following factors:¶
- (A) The type of transplant (i.e., autologous or allogeneic);¶
- (B) The specific diagnosis of the individual;¶
- (C) The stage of illness (i.e., in remission, not in remission, in second remission);¶
- (D) Satisfactory antigen match between donor and recipient in allogeneic transplants;¶
- (c) All alternative treatments with a one-year survival rate comparable to that of bone marrow transplantation must have been tried or considered.¶
- (2) Allogeneic transplants will be approved for payment only when there is a minimum of 5-out-of-6 antigen match for bone marrow and peripheral stem cell transplants, or 4-out-of-6 match for cord blood transplants, considering the HLA-A, B, and DR loci. Donor search costs up to an amount of \$15,000 will be covered only if prior authorized.¶
- (3) Donor leukocyte infusions are covered only when: ¶
- (a) An early failure or relapse post allogeneic bone marrow transplant occurs; and ¶
- (b) Peripheral stem cells are from the original donor.
- (4) The following are contraindications for autologous and allogeneic bone marrow, autologous and allogeneic peripheral stem cell and allogeneic cord blood transplants:¶
- (a) Irreversible terminal state (moribund or on life support);¶
- (b) An irreversible disease of any other major organ system likely to limit life expectancy to five (5) years or less;¶
- (c) Positive HIV test results;¶
- (d) Positive pregnancy test.¶
- (5) The following may be considered contraindications to the extent the evaluating transplant center hospital and/or the specialist who completed the comprehensive evaluation of the client believe these condition(s) may interfere significantly with the recovery process:¶
- (a) Serious psychological disorders;¶
- (b) Alcohol or drug abuse.¶
- (6) The Division of Medical Assistance Programs Health Systems Division (Division) will prior authorize and reimburse for autologous and allogeneic bone marrow, autologous and allogeneic peripheral stem cell and allogeneic cord blood transplants only if:¶
- (a) All Division criteria are met; and ¶
- (b) Both the transplant <del>center</del><u>hospital</u>'s and the specialist's evaluations recommend that the transplant be authorized; and¶
- (c) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141- $\frac{0.052383}{0.0000}$ .
- (7) The Division will prior authorize and reimburse for autologous and allogeneic bone marrow, autologous and allogeneic peripheral stem cell and allogeneic cord blood transplants for pediatric solid malignancies only if:¶
- (a) Requirements of  $\overline{OAR}$  410-124-0080(6)(a), (b) and (c) are met; and  $\P$
- (b) There is documentation of a morphology code listed on the currently funded line for pediatric solid tumor in the Prioritized List of Health Services adopted under OAR 410-141- $\frac{0.052}{0.00}$ 3830.¶
- (8) Prior authorization for harvesting of autologous bone marrow or peripheral stem cells does not guarantee reimbursement for the transplant; the patient must meet the criteria specified above and in <u>OAR</u> 410-124-0020 at the time the transplant is performed.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

### **CHANGES TO RULE:**

#### 410-124-0090

Criteria and Contraindications for Harvesting Autologous Bone Marrow and Peripheral Stem Cells ¶

- (1) The following are contraindications for the harvesting and storage of autologous bone marrow or peripheral stem cells for a potential transplant. The potential transplant recipient has:¶
- (a) Irreversible terminal state (moribund or on life support);¶
- (b) An irreversible disease of any other major organ system likely to limit life expectancy to five (5) years or less;¶
- (c) Positive HIV test results;¶
- (d) Positive pregnancy test.¶
- (2) The following may be considered contraindications for the harvesting and storage of autologous bone marrow or peripheral stem cells for a transplant to the extent the evaluating transplant centerhospital and/or the specialist who completed the comprehensive evaluation of the client believe these condition(s) may interfere significantly with the recovery process. The potential transplant recipient has:¶
- (a) Serious psychological disorders;¶
- (b) Alcohol or drug abuse.¶
- (3) The Division of Medical Assistance Programs Health Systems Division (Division) will prior authorize and reimburse for the harvesting and storage of autologous bone marrow or autologous peripheral stem cells for a potential transplant recipient only if:¶
- (a) All Division criteria are met; and ¶
- (b) Both the transplant  $\frac{\text{center}}{\text{hospital}}$ 's and the specialist's evaluations recommend that the transplant be authorized; and  $\P$
- (c) The ICD-10-CM diagnosis code(s) and the CPT bone marrow or peripheral stem cell harvesting for transplantation procedure code(s) are paired on a currently funded line on the Prioritized List of Health Services adopted under OAR 410-141-0523830; and ¶
- (d) There is documentation of a morphology code listed on the currently funded line for pediatric solid tumor in the Prioritized List of Health Services adopted under OAR 410-141-0523830; and  $\P$
- (e) The client's marrow meets the clinical standards of remission at the time of storage; and ¶
- (f) A board certified hematologist/oncologist with specific experience in bone marrow transplant (BMT) services (i.e., cryopreservation and immunosuppressive treatment) has recommended the storage of autologous bone marrow or peripheral stem cell collection for possible future transplant/reinfusion; and ¶
- (g) The client has no contraindications for the harvesting and storage of autologous bone marrow or peripheral stem cells; and  $\P$
- (h) The client has no contraindications for bone marrow transplant or peripheral stem cell transplant.¶
- (4) Prior authorization for harvesting of autologous bone marrow or peripheral stem cells does not guarantee reimbursement for the transplant. The client must meet the criteria specified in this rule and OAR 410-124-0080, and the transplant must be prior authorized by the Division before reimbursement will be approved.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

#### **CHANGES TO RULE:**

#### 410-124-0100

Criteria and Contraindications for Liver and Liver-Kidney Transplants

- (1) Prior authorization for liver or liver-kidney transplants will be approved only for a client in whom irreversible, progressive liver disease has advanced to the point where conventional therapy offers no prospect for prolonged survival, there is no reasonable alternative medical or surgical therapy and the client's five (5) year survival rate, subsequent to the transplant, is at least 20 percent as supported by medical literature.¶
- (2) Liver-kidney transplant is covered only for a medically documented diagnosis of Caroli's disease (ICD-10-CM Q44.6).¶
- (3) The following are contraindications for liver or liver-kidney transplants:¶
- (a) Incurable and untreatable malignancy outside the hepatobiliary system;¶
- (b) Terminal state due to diseases other than liver disease;¶
- (c) Uncontrolled sepsis, or active systemic infection;¶
- (d) HIV positive test results;¶
- (e) Active alcoholism or active substance abuse;¶
- (f) Alternative effective medical or surgical therapy;¶
- (g) Presence of uncorrectable significant organ system failure other than liver (excluding short-bowel syndrome or congenital intractable diarrhea).¶
- (4) The following may be considered contraindications to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe these condition(s) may interfere significantly with the recovery process:¶
- (a) Crigler-Najjar Syndrome Type II;¶
- (b) Amyloidosis;¶
- (c) Other major system diseases affecting brain, lung, heart, or renal systems;¶
- (d) Major, not correctable congenital anomalies;¶
- (e) Serious psychological disorders.¶
- (5) The transplant center will review for current risk of alcohol or other substance abuse and risk of recidivism and will inform the Division of Medical Assistance Programs (Division) of its findings prior to the provision of the transplant.¶
- (6) The Division will only prior authorize and reimburse for liver and liver-kidney transplants if: ¶
- (a) All Division criteria are met; and ¶
- (b) Both the transplant center's and the specialist's evaluations recommend that the transplant be authorized; and¶
- (c) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141-0520.

Statutory/Other Authority: ORS 413.042

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

### CHANGES TO RULE:

#### 410-124-0105

Criteria and Contraindications for Intestine and Intestine-Liver Transplants

- (1) Prior authorization for intestine and intestine-liver transplants will be approved only for:¶
- (a) A client who has failed Total Parenteral Nutrition (TPN) or who has developed life-threatening complications from TPN:¶
- (b) A client in whom irreversible, progressive intestine and/or liver disease has advanced to the point where conventional therapy offers no prospect for prolonged survival, there is no reasonable alternative medical or surgical therapy and the client's five (5) year survival rate subsequent to the transplant, is at least twenty (20) percent as supported by the medical literature.¶
- (2) Intestine and Intestine-Liver transplant is covered only for a medically documented diagnosis of Short Bowel Syndrome and for patients age 5 years or under with diagnosis of ICD-10-CM K55.0-K55.9, ICD-10-CM K91.2, or ICD-10-CM P77.9.¶
- (3) Small intestine transplant using a living related donor is considered investigational and will not be covered by The Division of Medical Assistance Programs (Division).¶
- (4) The following are contraindications for intestine or intestine-liver transplants:¶
- (a) Incurable and untreatable malignancy outside the hepatobiliary system;¶
- (b) Terminal state due to diseases other than liver or intestinal disease;¶
- (c) Uncontrolled sepsis, or active systemic infection;¶
- (d) HIV positive test results:¶
- (e) Alternative effective medical or surgical therapy;¶
- (f) Presence of uncorrectable significant organ system failure other than liver or Short-Bowel Syndrome.¶
- (5) The following may be considered contraindications to the extent that the evaluating transplant center and/or specialist who completed the comprehensive evaluation of the client believe these condition(s) may interfere significantly with the recovery process:¶
- (a) Crigler-Najjar Syndrome Type II:¶
- (b) Amyloidosis;¶
- (c) Other major system diseases affecting brain, lung, heart, or renal systems;¶
- (d) Major, non-correctable congenital anomalies;¶
- (e) Serious psychological disorders.¶
- (6) The Division will prior authorize and reimburse for intestine and intestine-liver transplant if:¶
- (a) All Division criteria are met; and ¶
- (b) Both the transplant center's and the specialist's evaluations recommend that the transplant be authorized; and ¶
- (c) The ICD-10-CM diagnosis code(s) and CPT procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141-0520.

Statutory/Other Authority: ORS 413.042

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

#### 410-124-0120

Criteria and Contraindications for Simultaneous Pancreas-Kidney and Pancreas After Kidney Transplants(1) Prior authorization for a Simultaneous Pancreas-Kidney (SPK) or Pancreas after Kidney (PAK) transplant will be approved only for a client in whom irreversible kidney and/or pancreatic disease has advanced to the point where conventional therapy offers no prospect for prolonged survival, there is no reasonable alternative medical or surgical therapy and the client's five (5) year survival rate, subsequent to the transplant, is at least 20 percent as supported by medical literature.¶

- (2) Simultaneous pancreas-kidney (SPK) transplant is covered only for Type I diabetes mellitus with end stage renal disease (ICD-10-CM codes E10.21, E10.22, E10.29, E10.21, E10.65).¶
- (3) Pancreas after kidney (PAK) transplantation will be considered for clients suffering from insulin dependent Type I diabetes after prior successful renal transplant. Pancreas after kidney (PAK) transplant is covered only for Type I diabetes mellitus (ICD-10-CM codes E10.8-E10.11, E10.31, E10.36, E10.39-E10.40-E10.41, E10.44, E10.49, E10.311, E10.319, E10.321, E10.329, E10.331, E10.339, E10.349, E10.351, E10.359, E10.610, E10.618, E10.620-E10.622, E10.628, E10.630, E10.638-E10.649, E10.69, T86.10-T86.13, T86.19, T86.890-T86.92, T86.898-T86.99¶
- (4) The following are contraindications to SPK and PAK transplants:¶
- (a) Uncorrectable severe coronary artery disease;¶
- (b) Major irreversible disease of any other major organ system likely to limit life expectancy to five years or less;¶ (c) HIV positive test results.¶
- (5) The following may be considered contraindications to the extent that the evaluating transplant center and/or the specialist who completed the comprehensive evaluation of the client believe these condition(s) may interfere significantly with the recovery process:¶
- (a) Serious psychological disorders;¶
- (b) Drug abuse or alcohol abuse.¶
- (6) The Division of Medical Assistance Programs (Division) will only prior authorize and reimburse for Simultaneous Pancreas-Kidney (SPK) or Pancreas after Kidney (PAK) transplants if:¶
- (a) All Division criteria are met; and ¶
- (b) Both the transplant center's and the specialist's evaluations recommend that the transplant be authorized; and ¶
- (c) The ICD-10-CM diagnosis code(s) and CPT transplant procedure code(s) are paired on the same currently funded line on the Prioritized List of Health Services adopted under OAR 410-141-0520. Statutory/Other Authority: ORS 413.042

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

410-124-0140

Kidney Transplants ¶

- (1) Kidney transplants do not require prior authorization when accomplished in-state.¶
- (2) Out-of-state kidney transplant services are prior authorized by the Division or the Fully Capitated Health Plan (FCHPHealth Systems Division (Division) or the Managed Care Entity (MCE):¶
- (a) Submit the request to the FCHPMCE or Division;¶
- (b) The request must contain the following information: ¶
- (A) Name and Medical Assistance Identification number of the client;¶
- (B) A description of the condition which necessitates a transplant; ¶
- (C) The results of any evaluation performed by an in-state provider of kidney transplant services;¶
- (D) An explanation of the reason out-of-state services are requested.

RULE SUMMARY: The transplant rules are outdated, the transplant criteria in rule are no longer current with today's medical advancements.

**CHANGES TO RULE:** 

410-124-0160

Cornea Transplants ¶

- (1) Cornea transplants do not require prior authorization when accomplished in-state. ¶
- (2) Out-of-state corneal transplant services are prior authorized by the Division or the Fully Capitated Health Plan (FCHPHealth Systems Division (Division) or the Managed Care Entity (MCE):¶
- (a) Submit the request to the FCHPMCE or Division;¶
- (b) The request must contain the following information: ¶
- (A) Name and Medical Assistance Identification number of the client;¶
- (B) A description of the condition which necessitates a transplant; ¶
- (C) The results of any evaluation performed by an in-state provider of cornea transplant services;¶
- (D) An explanation of the reason out-of-state services are requested.