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TO: All County Administrators and Medical Consultants for California Children's Services Program, Specialists at California Children's Services Transplant Centers of Excellence/Special Care Centers, and Integrated Systems of Care Division Staff

SUBJECT: Blood, Tissue, and Solid Organ Transplants

I. PURPOSE

This Numbered Letter (NL) establishes policy and procedures for the review and authorization of blood, tissue, and solid organ transplants. The California Children's Services (CCS) Program publishes this NL under the Program's authority to authorize services that are medically necessary to treat CCS-eligible conditions.[1, 2, 3]

II. BACKGROUND

Innovations in transplantation have transformed the survival and quality of life for patients with various diseases and end-organ dysfunction in whom traditional therapies have failed. In a transplant, cells, tissue, fluids, or one or more organs is removed from a donor and placed in a recipient to substitute for a damaged or missing counterpart. Donor organ procurement may occur in the same physical location with immediate transplantation or at a distant site with transportation for delayed fresh transplantation or cryopreservation and storage for later thawing and transplantation. Transplantation within the same body is called an autograft and typically involves cryopreservation and storage of acquired material, interval treatment to remove abnormal cells in the acquired material and/or the host, and ultimate replacement into the patient. Allografts involve procurement of one or more

[1] 22 Cal. Code Regs. § 41515.1 et. seq.
[2] 22 Cal. Code Regs. § 41700
[3] 22 Cal. Code Regs. § 41740

organs or cells from either a living donor or an individual with brain or circulatory death for transplant into a recipient.

Federal oversight of the nation's organ and blood stem cell transplant systems and for initiatives to increase organ and blood stem cell donations in the United States (U.S.) is the responsibility of the Division of Transplantation (DoT) in the Department of Health and Human Services. The United Network for Organ Sharing (UNOS) administers the only Organ Procurement and Transplantation Network (OPTN) in the U.S. The Be The Match Registry is a state parallel system that provides support to individuals who need hematopoietic stem cell transplant (HSCT) that may be derived from bone marrow, peripheral blood, or cord blood through the C.W. Bill Young Cell Transplantation Program. Cord blood units are available from numerous banks; the National Cord Blood Inventory (NCBI) is responsible for building a genetically and ethnically diverse inventory of high-quality umbilical cord blood for transplantation.

The Centers for Medicare and Medicaid Services (CMS) provides regulatory oversight of the U.S. adult and pediatric transplant Centers of Excellence (COE). Medicare Conditions of Participation for organ transplant programs were established in 2007, and CMS maintains approval according to criteria that reflect the overall volume and unique complexity associated with each type of transplant. Pediatric COEs are approved to treat individuals up to age 18, while adult centers treat those 18 years of age and older.

A. CCS Program Transplant Special Care Centers:

1. California pediatric and adult COEs with current approval by CMS and Medi-Cal may apply for approval to treat CCS Program beneficiaries at a CCS Program Transplant Special Care Center (SCC). Transplant SCCs are authorized to provide a group of related health care services under Service Code Grouping (SCG) 03 which includes all Current Procedural Terminology (CPT®) codes available in SCG 01 (physician services) and SCG 02 (SCC services), as well as a few codes unique to transplants. Additional care needs are adjudicated through the Service Authorization Request (SAR) process.

2. Transplant COEs with current CCS Program approval as Transplant SCCs can be found on the CCS Program Website.[4]

    a. Current categories of CCS-approved COEs include hematopoietic (blood or bone marrow) stem cell, heart and/or lung, and liver.

    b. Intestine and multivisceral transplants that include one or more gastrointestinal tract organs (e.g., stomach, pancreas, liver, and/or small

[4] Special Care Centers by Center Type

intestine) and/or kidney are most commonly performed in liver transplant COEs.

c. CCS Program beneficiaries aged 18 years and older may undergo kidney-pancreas transplants at Medi-Cal approved adult COEs.

d. Performance of kidney, autologous islet cell, and corneal transplants are not required to be approved by Medi-Cal or the CCS Program.

3. CCS beneficiaries 18-20 years of age may be cared for either by a pediatric or adult COE, aligning the individual needs of the child with the expertise of the COE.

4. COEs looking to apply for CCS Program approval are evaluated on a case-by-case basis. Submit applications to the California Department of Health Care Services (DHCS) Integrated Systems of Care Division (ISCD) facility review inbox at CCSFacilityReview@dhcs.ca.gov. It is also recommended to send an alert that an application has been sent to the DHCS ISCD Medical Policy inbox at ISCD-MedicalPolicy@dhcs.ca.gov.

III. POLICY

The following represent the current criteria for requests to the CCS Program for medical eligibility; initial evaluation; recipient screening, including human leukocyte antigen (HLA) and genetic testing; family-member screening and matched-unrelated donor (MUD) search; organ procurement and transplantation; inpatient hospital stays; and post-transplantation services for CCS Program beneficiaries.

A. Transplant Types

Medi-Cal separates transplants into “Major” Organ Transplants (MOT) – which includes hematopoietic stem cell, heart, intestine, kidney-pancreas, liver, lung, and multivisceral; and non-MOT – which includes kidney, islet cell, and corneal.

Benefit standardization under the California Advancing and Innovating Medi-Cal (CalAIM) initiative is described in the All-Plan Letter (APL) 21-015 or any superseding APL. Under its provisions, MOTs are carved in to Medi-Cal Managed Care Health Plans (MCP) effective January 1, 2022. The implications of this guidance for the CCS Program are that MCPs in Whole Child Model (WCM) counties are responsible for all transplants for their members, while CCS Program is responsible for all transplants in classic CCS counties.

A list of transplant request types along with adjudication responsibility by county type and insurance status is provided in IV. Policy Implementation and in

Attachment 1 – Transplant Responsibilities for Medi-Cal beneficiaries less than 21 years of age by Type of County, Transplant, and Service. Additional information is available in the Medi-Cal Provider Manual, which contains instructions relevant to all types of transplants.[5]

B. Transplant Recipient Evaluation Requests

1. Evaluation requests should be submitted as an electronic Service Authorization Requests (eSARs) along with supporting documents that include clinical evaluation by a CCS-paneled physician using the Provider Electronic Data Interchange (PEDI) web portal.[6] In classic CCS counties, evaluation requests will receive expedited adjudication by CCS Program staff, which involves adjudication by a nurse evaluator, with physician consultation as needed, and does not involve the ISCD Transplant SAR Team.

2. Evaluation requests should include the following two SARs, each for a period of 180 days or through the current program eligibility period:

   a. Facility: SCG 03 to the Transplant COE.[7]

   b. Physician: SCG 01 to the CCS-paneled physician or surgeon who will perform the transplant.

Transplant-specific medical-necessity determination is based on Medi-Cal selection criteria available to Medi-Cal approved COEs. Denials require medical consultant approval in classic CCS counties.

C. Transplant Screening Requests

1. All proposed recipients of an allograft require recipient and donor testing to optimize the matching process. These include blood typing; cross-matching; human leukocyte antigen (HLA) testing, also known as tissue typing or histocompatibility testing; and serologic screening for transmissible infections. Commonly used procedure codes for these tests are covered under SCG 01, 02, and 03.

2. Recent innovations in precision medicine harness systems biology to understand the molecular basis of an individual patient's disease and to design and apply targeted approaches to medical treatment and donor selection in the transplant process. CPT codes not included in SCG 01, 02, or 03 require SAR approval and must be ordered or prescribed by a CCS-

[5] Medi-Cal Provider Manual
[6] Provider Electronic Data Interchange (PEDI)
[7] Service Authorization Request Tools

paneled medical geneticist or a CCS-paneled COE transplant team physician. These SARs will receive routine adjudication by CCS Program staff.

D. Donor Search and Evaluation Requests

1. Donor Types:

   a. Family member – The optimal donor is a histocompatible matched relative, usually a sibling with identical HLA tissue typing. Haplocompatible individuals include siblings, parents, or grandparents with 50% match and may be used in rare circumstances.

   b. Unrelated donor – In the absence of an available family member, a search is initiated to identify compatible unrelated living or deceased donors using one of the organ and blood stem cell donation systems operated by the DoT as described in Section II, above.

2. Requests for donor evaluation must include:

   a. Submission of a request for SAR modification to the recipient SCG 03 with codes for donor evaluation, if performed by the same physician at the same institution as the transplant.

   b. Evaluations to be performed by a separate physician at an institution different from the transplant COE must be submitted by the requesting transplant COE and require unique facility and physician SARs specific to the donor. Major organ transplant facilities must be approved as Medi-Cal COEs for the specific organ type for the SARs to be authorized. The donor facility bills with a UB-04 claim form using the recipient's Medi-Cal number.

   c. Any procedure codes not covered by the donor program or included in the SCGs 01, 02, and 03.

   d. The name, date of birth, and relation to the transplant recipient (if any) of the donor must be added to all recipient transplant SARs in the Special Instructions section.

   e. Providers must submit donor requests via eSAR using the PEDI web portal for recipients who reside in classic CCS counties and notify ISCD through Right Fax: (916) 440-5308 or email: CCSPhysicianReview@dhcs.ca.gov. These requests will undergo routine adjudication by the ISCD Transplant SAR Team under the direction of an ISCD Medical Consultant.

3. Requests for MUD search:

   a. Require a separate outpatient facility SAR for a period of 180 days or through the current program eligibility period and CPT code 38204.

   b. Other acceptable CPT codes not included in the SCGs include but are not limited to:

      (1) 81403 – Mopath procedure level 4

      (2) 81407 – Mopath procedure level 8

      (3) 86828 – HLA Class I/II Antibody Qual

      (4) 86830 – HLA Class 1 Phenotype Qual

   c. Providers must submit MUD search requests via eSAR using the PEDI web portal for recipients who reside in classic CCS counties and notify ISCD via the DHCS CCS Program Physician Review mailbox: CCSPhysicianReview@dhcs.ca.gov and require review by ISCD Medical Consultant or designee.

E. Transplantation Requests:

1. Must be submitted by a COE prior to the requested transplant date. Retroactive authorization will not be given.

2. Must be submitted along with supporting documents using the PEDI web portal. It is important that counties neither delete these requests nor adjudicate them, as they must await ISCD Medical Consultant review.

3. Encompass both organ procurement and transplant components. Both may be requested simultaneously. Alternatively, a transplant request for the recipient may be submitted first, followed by a living donor organ procurement request. Deceased donor requests are submitted retroactively.

4. Require medical necessity determination by an ISCD Medical Consultant or designee for transplant recipients in classic CCS counties.

5. Must be communicated to ISCD directly via Right Fax: (916) 440-5308 or email: CCSPhysicianReview@dhcs.ca.gov. Messages received through CMS Net or personal email will be returned in order to centralize the process and reduce the potential for missed communications.

6. Require case management from CCS county Program staff.

7. To send a CCS Program beneficiary to another state for transplantation or to perform out-of-state donor evaluation and/or organ procurement may be eligible as per N.L. 09-1119.[8]

8. Consist of the following SARs, each for a period of 180 days or through the current program eligibility period:

    a. Donor organ procurement:

        (1) A donor's physician and facility may differ from those of the transplant recipient.

        (2) For recipients who reside in classic CCS counties, requests for authorization of organ acquisition from a deceased donor for an authorized transplant must be submitted retroactively and adjudicated by the CCS Program County or ISCD staff. Such decisions do not require Medical Consultant approval. It is not necessary to forward an organ acquisition invoice to ISCD.

        (3) Requests for organ procurement from a living donor for all types of transplants should include the donor's name, date of birth, relationship (if any) to the recipient, documentation of HLA histocompatibility, and medical clearance for donation. For recipients from classic CCS counties, this information should be included under Special Instructions on the recipient's SCG 03.

        (4) If the physicians for donor and recipient are different, a separate SCG 01 with appropriate CPT codes should be requested for each physician. An inpatient SAR specific to the donor's organ procurement location is required if it is different from the recipient facility.

        (5) All organ procurement claims should be submitted by the donor facility on a UB-04 claim form using the recipient's Medi-Cal number.

        (6) These SARs do not require adjudication by an ISCD Medical Consultant; they are adjudicated by Independent County and ISCD clinicians.

    b. Recipient:

[8] CCS N.L. 09-1119 Authorization of Out of State Service Requests

(1) Special Care Center Facility SAR: SCG 03 to the COE for 1 Unit.

(2) Physician SAR: SCG 01 to the CCS-paneled physician who will perform the transplant. Standard codes for each type of transplant are listed in Attachment 2. This SAR must specify the transplant COE location under Special Instructions.

(3) These SARs must be adjudicated by an ISCD Medical Consultant or designee for recipients in classic CCS counties.

9. Must include the following documentation:

a. A request for organ procurement requires a comprehensive COE workup and complete packet, as the decision to perform a transplant precedes procurement of blood, cells, or organ(s) to be transplanted. Children transferred from affiliated hospitals must undergo an independent workup by the COE.

b. Clinical notes from the physician performing the transplant, which must include:

(1) Complete clinical history, including the dates and outcomes of previous therapeutic interventions.

(2) Demonstration that relevant alternative treatments have been exhausted and the request for transplantation is both clinically appropriate and medically necessary based on the child's clinical history.

(3) Recommendation for the specific transplantation proposed.

(4) Documentation that there are no absolute contraindications for the transplant procedure or anesthesia, (if indicated).

c. From the requesting Transplant COE Team:

(1) Transplant team notes, with a list of meeting attendees and a summary of the discussion, including:

(a) Medical indications for the transplant;

(b) Reasons why alternative approaches are not recommended or have been exhausted; and

(c) Non-medical factors relevant to the candidate's suitability for transplant, including psychosocial characteristics.

(2) All relevant laboratory and imaging results.

(3) Social work assessment of the recipient's mental health, emotional wellness, and available support systems and resources.

(4) Nutrition assessment from the registered dietitian stating that the child is metabolically fit for the procedure.

(5) A listing of all research studies in which the recipient is participating that includes the study title and purpose, information on the study arm if available, and a statement regarding whether study participation is likely to impact the transplantation.

(6) If the beneficiary is participating in a qualifying clinical trial, as defined by the Consolidated Appropriations Act, 2021,[9] the trial's CCS-paneled principal investigator and the CCS-paneled physician specialist who is treating the beneficiary for the condition that qualifies them for participation in the investigational protocol must complete and sign a "Medicaid Attestation form on the Appropriateness of the Qualified Clinical Trial".[10]

(7) For children being considered for HSCT in which ultimate recommendation for transplant depends on the outcome of the conditioning process, it is recognized that Team approval will consist of two-steps and that social work and nutritional assessments may not be included until the transplant is requested.

F. Chimeric Antigen Receptor T (CAR-T) Cell Therapy:

1. CAR-T cells are genetically engineered to produce an artificial T-cell receptor for use in immunotherapy. This section relates to CAR-T products used to treat beneficiaries with blood malignancies.

2. CAR-T cell therapy requests must follow all instructions provided in NL 07-1019 or the newest published CCS Program CAR-T policy, with the following clarifications.

3. The CAR-T cell therapy preauthorization process can be split into two phases:

[9] Consolidated Appropriations Act, 2021
[10] Medicaid Attestation form on the Appropriateness of the Qualified Clinical Trial

a. In phase I, the provider requests collection and cryopreservation of hematopoietic stem cells (HSC). This includes submission or modification of a physician SCG 01 SAR adding the appropriate CPT codes listed on Attachment 2 (1 unit each). Include a note in Special Instructions to identify that this is for CAR-T.

b. Phase II includes the request for CAR-T and its administration code(s):

(1) Each type of CAR-T has its own product-specific Healthcare Common Procedure Coding System (HCPCS) code, e.g., Q2042 for tisagenlecleucel (Kymriah), that must be requested on an outpatient SAR.

(2) Thaw and infusion of the HSC must be requested (1 unit each) as a modification to the physician SCG 01 SAR using CPT codes listed on Attachment 2.

(3) CAR-T investigational trials must follow instructions outlined above in III.9.c.(6) and may require additional CPT codes on the provider SCG 01 SAR.

4. CAR-T and transplant-related therapies are medical benefits but not pharmacy benefits.

5. Providers must submit eSARs with supporting documents for both phases of the CAR-T request process using the PEDI web portal.

6. Given the urgent nature of most CAR-T procedures, providers of children who reside in classic CCS counties are encouraged to notify the ISCD Transplant Team via the DHCS CCS Program Physician Review mailbox: CCSPhysicianReview@dhcs.ca.gov.

7. Independent classic counties that choose to adjudicate CAR-T requests per NL 07-1019 or the newest published CCS Program CAR-T policy must ensure that all steps above are completed and may contact the ISCD Transplant Team for guidance. Deferral to ISCD is welcome.

8. The treating Hematology/Oncology SCC must bill CAR-T using the UB 04 claim form or electronically using the 837I. Product-specific codes, including T-codes for specific CAR-T products, are not accepted by the Medi-Cal payment system.

G. Fertility Preservation:

1. Infertility is a common long-term complication of allogenic HSCT. Conditioning regimes, particularly those involving alkylating chemotherapeutic agents and total body irradiation, affect as many as 80% of HSCT recipients who survive to adulthood. Infertility rates are only slightly higher than in the general population for patients who undergo solid organ transplants.

2. Informed consent prior to HSCT must include counseling with the patient and parents/caregivers about the risk of long-term adverse outcomes, including infertility. An infertility risk assessment should include the patient's underlying disease, co-morbidities, age, treatment history, and planned conditioning regimen. An overview of fertility preservation techniques tailored to the unique clinical situation should be presented followed by an in-depth discussion about the best applicable strategies to meet their specific needs.

3. Fertility preservation for allogenic HSCT recipients is a rapidly evolving area of reproductive medicine. Currently available options include the pre-treatment collection and cryopreservation of germinal tissue in pre-pubertal girls and boys, and of gametes in post-pubertal individuals. At this time, fertility preservation is not a CCS benefit.

H. Inpatient Hospitalization and Post-Transplantation Service Requests:

1. These include post-transplant SAR modifications that add CPT codes, address complications, and/or extend provider and COE service duration. Questions may be directed to the ISCD Transplant Team via the DHCS CCS Program Physician Review mailbox: CCSPhysicianReview@dhcs.ca.gov.

2. Such requests must be submitted as electronic SARs, along with supporting documents using the PEDI web portal.

3. These requests will be processed routinely by CCS Program staff and do not require ISCD Medical Consultant review.

I. Second Transplant Requests, including relisting due to transplant failure, require a new and complete transplant request as described above in Section III.D.

IV. POLICY IMPLEMENTATION

A. Medical eligibility for the CCS Program for all children recommended to receive any type of transplant is evaluated by CCS Program staff through routine channels.

B. For children residing in Whole Child Model (WCM) counties:

1. For children enrolled in a MCP, all transplants are carved in to WCM MCP contracts. Requests for evaluation, transplant, follow-up, and case management for children who are medically eligible for the CCS Program should be directed to the MCP.

2. For children with fee-for-service Medi-Cal:

   a. CCS Program covers all medically necessary transplants related to a CCS-eligible condition.

   b. Medi-Cal covers rare transplants related to a CCS-ineligible condition. For questions, please contact the ISCD Transplant Team via the DHCS CCS Program Physician Review mailbox: CCSPhysicianReview@dhcs.ca.gov

3. Requests for transplants in children who are CCS State only beneficiaries must be directed to their other health care insurance, if applicable, as the CCS Program is the payer of last resort.

C. For children residing in classic CCS counties:

1. Kidney, corneal, and islet cell transplants:

   a. Requests for transplant in children with a CCS-eligible condition should be sent to CCS Program.

      (1) For CCS Program Independent Counties, all requests will be reviewed and adjudicated by local County CCS Program medical consultants.

      (2) For CCS Program Dependent Counties, all requests will be reviewed and adjudicated by ISCD medical consultants.

   b. For transplant candidates with an underlying CCS-eligible condition, requests for authorization and responsibility for coverage and related case management for MCP enrollees should be directed to the CCS Program.

   c. For children who are CCS State only beneficiaries, non-MOT requests must be directed to their other health care insurance, if applicable, as the CCS Program is the payer of last resort.

2. HSCT, heart, intestine, kidney-pancreas, liver, lung, and multivisceral transplants:

   1. Only an ISCD Medical Consultant or their designee can approve these transplant types.

2. County CCS Program offices are responsible for case management for these children.

3. Other health care insurance, if applicable, covers all transplants in CCS State only beneficiaries, as the CCS Program is the payer of last resort.

4. Post-HSCT requests for additional stem cell infusions (tandem or double autologous transplants) or donor lymphocyte infusions (DLIs) or second unique transplants must be deferred to ISCD for review by the Medical Consultant or designee as a new and distinct transplant.

3. The following requests from CCS-approved COEs for the specific organ transplant involved should be considered as routine SARs and adjudicated by County CCS Program offices (for independent county residents) or ISCD (for dependent county residents):

   a. Transplant evaluation;

   b. Hospitalization;

   c. Post-transplant services; and

   d. SAR modifications that add CPT codes for transplant-related or unrelated services, as long as they do not represent new and distinct transplant requests.

If you have any questions regarding this NL, email the ISCD Medical Policy team at ISCD-MedicalPolicy@dhcs.ca.gov.

Sincerely,

ORIGINAL SIGNED BY

Cortney Maslyn, Chief
Integrated Systems of Care Division
Department of Health Care Services

Attachments:

Attachment 1 – Adjudication Responsibilities by SAR and County Type

Attachment 2 – List of Commonly-Used Transplant Current Procedural Terminology (CPT®)