SUBJECT: Special Formula

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A. POLICY STATEMENT

Special formulas are nutritional preparations recommended by a dietitian and medically requested by a physician, physician assistant (PA), or advanced practice registered nurse (APRN) to help ensure nutritional intake adequate for optimal growth and development of children and youth with qualifying medical conditions. Services of the Children and Youth with Special Health Care Needs (CYSHCN) Special Formula program are delivered by licensed dietitians (RD, RDN, LD) who conduct nutrition assessments, nutrition education/counseling, care coordination, and provide ordered special formulas to enrolled clients.

B. DEFINITIONS

1. **Regular Infant Formula**: A commercially available, nutritionally complete formula designed for the general population of healthy infants who are unable to receive breast milk. Regular infant formula is typically cow's milk-based, although soy, hydrolyzed, and lactose-free versions are available for specific dietary needs.
2. **Special Formula**: A formula designed for pediatrics with specific medical conditions or dietary requirements that cannot be met with regular infant formula. This includes hydrolyzed, amino acid-based, or elemental formulas as well as oral nutritional supplements (ONS) used to provide additional calories, protein, vitamins, and minerals when regular food intake is insufficient for needs.
3. **Metabolic Formula**: A specialized medical food used to manage inborn errors of metabolism, such as phenylketonuria (PKU), maple syrup urine disease (MSUD), or other metabolic disorders. Metabolic formulas are tailored to meet the specific nutrient needs of individuals with these conditions, providing a precise balance of amino acids, vitamins, and minerals required for normal growth and development while restricting specific nutrients that may be harmful to the individual's health.

C. STANDARDS

1. Eligibility Criteria:
    a. Citizenship: Must be a US citizen or have lawful permanent resident status.
    b. Residency: Must be a South Carolina resident.

c. Age: Under 18 years old (services may be provided until the last day of the month of the 18th birthday).
d. Income: Current Medicaid enrollment or household income at or below 250% federal poverty level in accordance with the Financial Assistance Services policy.
e. Clinical Criteria:
    1. Copy of a medical note (by a physician, PA, or APRN) from the preceding 12 months showing a qualifying diagnosis (including corresponding ICD code) in accordance with the Qualifying Diagnosis List Appendix 12 ;
    2. The qualifying diagnosis (Appendix 12) must relate to the need for special formula; and
    3. At least 25% of calories are provided by special formula.
f. Nutritional Criteria:
    1. Documented difficulty eating enough solid food to meet caloric needs must relate to the qualifying diagnosis (Appendix 12) and include one or more of these nutritional conditions listed below [Note: All above-listed eligibility criteria (Standard 1.a-e) must be met before any Nutritional Criteria is considered.]:
        a. Demonstrated difficulty swallowing or chewing;
        b. Clinically significant texture aversion issues;
        c. Medical diagnosis associated with hypermetabolism (e.g., spastic quadriplegia);
        d. Medical diagnosis associated with malabsorption (e.g., cystic fibrosis, Crohn's disease); and/or
        e. Delayed growth indicated by documented evidence of weight loss or regression in growth when formula is not received, as evidenced by standardized growth charts.
g. Special Consideration:
    1. Infants (children under the age of 12 months) with extenuating medical circumstances whose review by the CYSHCN Central Office (CO) Medical Consultant indicates need for special formula and/or supplement.
    2. Approval for a 6-month period, with review and re-approval required every 6-months or more often as determined by the CYSHCN CO Dietitian Consultant, may be considered for:
        a. Transition from tube feeding to oral feeding; or
        b. Temporary hypermetabolic state due to pending surgery.
    3. CYSHCN CO review and approval via 'CYSHCN Special Request' Ad Hoc Form (DPH 0758) is required for request for enrollment in the setting of documented diagnosis of the following:
        a. Autism with a documented failed swallow study;
        b. Eosinophilic esophagitis (EoE); or

c. Food Protein-Induced Enterocolitis Syndrome (FPIES).

2. Coverage and Limitations:
    a. CYSHCN will purchase 100% of the special formula that the CYSHCN Regional Dietitian determines necessary for eligible children, in excess of any formula provided though the WIC program, private insurance, and/or school system.
    b. CYSHCN does not approve or pay for regular infant formulas, which are not considered special formulas.
    c. Metabolic formulas are provided under the Metabolic Formula program.
    d. Special formula will not be approved for:
        1. Administration by gastric tube (if the child has Medicaid coverage, they should be referred to SC DHHS);
        2. Use during school hours (this should be covered by school nutrition programs); or
        3. When prescribed for behavioral feeding problems, allergy management, or undernutrition due to behavior modifying medications or other medications that suppress appetite.
        4. All other sources of third-party payment for special formula for which the child is eligible must be exhausted, including as applicable:
            a. Private health insurance coverage (Parent/guardian to provide verbal or written confirmation of plan denial of special formula. Document plan denial in client's record.);
            b. WIC program benefits;
            c. Medicaid waiver programs; and/or
            d. School nutrition programs and/or Individuals with Disabilities Education Act (IDEA) part B entitlements as listed on Individualized Education Plan (IEP) or approved 504 plan, see USDA-FNS Accommodating Children with Disabilities in the School Meal Programs.
3. CYSHCN CO review and approval of new applications for enrollment to the Special Formula program is required.
    a. Reapplications for special considerations (Standard 1.g) for continued enrollment require CO approval.
4. Medical Request for Special Formula:
    a. A medical request for special formula from the child's health care provider (physician, PA, or APRN) must be on file with DPH before an order for the formula can be made.
    b. The medical request must include:
        1. Date of issuance; and
        2. The client's full name and date of birth; and
        3. The formula name(s), quantity, duration, and directions for use; and

4. The provider's name, address, telephone number, degree classification, SC license number, and signature. The signature must be the original signature or e-signature. Rubber stamped signatures are not acceptable.

c. New medical requests are required **every 12 months** or when the formula changes.
d. The 'Medical Request for the Provision of CYSHCN Special Formula and/or Nutritional Supplements' (DPH 4006) may be used as a special formula medical request template, or the formula request may be documented via a provider's prescription.
e. CYSHCN cannot accept WIC prescriptions (DPH 2074).

5. Document in the Electronic Health Record (EHR).
   a. All health record documentation is entered in the EHR.
   b. If the EHR system experiences a system interruption, then follow the EHR Downtime Policy.
      1. References in this policy to DPH paper forms are provided for guidance during EHR downtime.
6. Record Updates:
   a. Care coordination contacts (and attempted contacts) with client/family are documented via 'CYSHCN Note' (DPH 1619A) in accordance with the client's acuity level (Appendix 16) and as needed.
   b. Provision of nutrition education/counseling to clients/families is documented via 'CYSHCN Note' (DPH 1619A) and if indicated via the 'CYSHCN Nutrition Assessment and Plan of Care: Infant and Child' Ad Hoc Form (DPH 1545).
   c. CYSHCN annual eligibility updates are required.
      1. Use of EHR Ad Hoc Forms 'CYSHCN Intake & Assessment' (DPH 4384), 'CYSHCN Eligibility Determination' (DPH 4501), and if indicated 'CYSHCN Nutrition Assessment and Plan of Care: Infant and Child' (DPH 1545) and 'CYSHCN Transition Readiness Flowsheet' (DPH 4333), are the minimal forms needed to ensure update status is complete.
      2. Request and if received file an updated medical note related to the child's qualifying diagnosis (Appendix 12) within the preceding year.
   d. Nutrition assessments are documented via the 'CYSHCN Nutrition Assessment and Plan of Care: Infant and Child' Ad Hoc Form (DPH 1545) every **six (6) months**, and more often if needed, based on the client's medical needs and/or nutritional status to determine ongoing need and amount of special formula to be authorized.
   e. Acuity levels (Appendix 16) will be reviewed at least annually and amended as needed.

f. Close the record and remove from caseload in accordance with the Documentation and Quality Assurance policy. If no services are requested over a 1-year period and there is a documented need for the child to remain enrolled on the Special Formula program, consult with the CYSHCN CO Dietitian Consultant.

D. PROCEDURES

1. Referring Provider (Physician, PA, or APRN) Responsibilities:
    a. For children not currently enrolled in the CYSHCN Special Formula program, referring provider sends the CYSHCN Services Request Form (DPH 4290) with supporting medical/nutrition documentation (Standard 1.e-f clinical/nutritional eligibility criteria) and medical request for formula (Standard 4) to CYSHCN Regional Office.
    b. Upon enrollment and for continuation of services, the referring provider determines the need for special formula and sends the following to CYSHCN Regional Office:
        1. Medical request for formula documented per Standard 4 and completed within the preceding 12 months or when formula changes; and
        2. Copy of medical notes, including anthropometrics, supporting the need for formula within the preceding 12 months and as requested.
2. CYSHCN Regional Office Responsibilities:
    a. Create an electronic health record if indicated.
    b. Verify that applicant meets Special Formula program eligibility requirements, per Standards 1-2.
    c. Obtain agency and program required consents, including 'General Consent for Health Services' (DPH 0788), 'Authorization to Release Health Information' (DPH 1623), and 'CYSHCN Client/Family Responsibilities' (DPH 3150).
    d. CYSHCN Regional Dietitian completes intake application with applicant/family, including EHR growth charts (DPH 0774 or 0775) and the following EHR Ad Hoc Forms: 'CYSHCN Nutrition Assessment and Plan of Care: Infant & Child' (DPH 1545), 'CYSHCN Intake & Assessment' (DPH 4384), 'CYSHCN Eligibility Determination' (DPH 4501), and if indicated, 'CYSHCN Transition Readiness Flowsheet' (DPH 4333).
        1. Documentation of the 'CYSHCN Nutrition Assessment and Plan of Care: Infant & Child' Ad Hoc Form (DPH 1545) must include the information listed below with attachments as needed:
            a. Documentation of one or more of the covered nutritional conditions listed in Standard 1.f;

b. A medical request for the formula from the child's health care provider in accordance with Standard 4;
c. Amount of formula provided by other sources (WIC, school);
d. Detailed description of all other non-formula calorie boosting/ protein boosting techniques that have been tried (if this is the first time formula has been requested for the child);
e. Estimated nutritional needs for, at a minimum, total calories and protein;
f. Complete 24-hour diet recall with calculations, at a minimum for total calories and protein (calculations must clearly indicate the percent of calories and protein provided by food versus the percent of calories and protein provided by formula);
g. Assessment of estimated needs for total calories and protein versus actual intake of total calories and protein (to document that nutritional needs are not being met by current intake without use of formula);
h. Capability to chew, swallow, or otherwise safely consume solid/semi-solid food and formula;
i. Method to consume formula: bottle, cup, syringe, etc.;
j. History of previous tube feedings/ consideration of tube feedings, if appropriate;
k. Current anthropometric measures and growth assessment (date of measures must be no more than 60 days before the nutrition assessment and/or formula request);
l. Interval medical/health history and pertinent medical diagnoses; and
m. Plan to monitor use of formula and progress with interventions and goals.

e. Notify the CYSHCN CO Dietitian Consultant of the completed application ready for review.
f. Upon application determination (approval or denial) by the CYSHCN CO Dietitian Consultant (or CO designee):
    1. CYSHCN Regional Nurse Unit Manager (or designee) will review the CO determination (approval or denial) and review the intake application and then complete a 'CYSHCN Referral Disposition' Ad Hoc Form (DPH 4503).
    2. CYSHCN Regional Office will notify the applicant/family and referring provider of enrollment approval or denial.
        a. If approved, mail the 'CYSHCN Special Formula Approval' letter, which is generated and uploaded in the client's

record by the CYSHCN CO Dietitian Consultant (or designee).

b. If denied, mail the 'CYSHCN Special Formula Denial' letter, which is generated and uploaded in the client's record by the CYSHCN CO Dietitian Consultant (or designee).

c. If application and/or formula request is denied, CYSHCN Regional Dietitian may resubmit the request based upon a change in medical/nutritional status or receipt of additional information from the child's provider.

g. Upon enrollment, the assigned CYSHCN Regional Dietitian will:

1. Document via 'CYSHCN Note' (DPH 1619A) care coordination contacts (and attempted contacts) with client according to the client's acuity level (Appendix 16) and as needed.
2. Document via 'CYSHCN Note' (DPH 1619A) and if indicated via the 'CYSHCN Nutrition Assessment and Plan of Care: Infant and Child' Ad Hoc Form (DPH 1545) the provision of nutrition education/counseling to clients/families.
3. Complete annual updates per Standard 6 and per the Care Coordination policy.
    a. Use of DPH EHR Ad Hoc Forms: 'CYSHCN Intake & Assessment' (DPH 4384), 'CYSHCN Eligibility Determination' (DPH 4501), and if indicated 'CYSHCN Nutrition Assessment and Plan of Care: Infant and Child' (DPH 1545) and 'CYSHCN Transition Readiness Flowsheet' (DPH 1545) are the minimal forms needed to ensure annual update is complete.
    b. At time of annual update, request an updated medical note related to the child's qualifying diagnosis (Appendix 12) dated within the preceding year and if indicated an updated medical request for formula (Standard 4) and upload to the client's record.
    c. Minimum contact attempts for annual update will follow those for routine matters as per the Overview and Definitions policy to include at least three (3) documented attempts to communicate with the client/family, one (1) of which must be a letter to the last known mailing address (unless mailing is noted as prohibited in the client's record). The 'CYSHCN Annual Eligibility' letter (with corresponding 'Annual Eligibility Update Worksheet' and 'Update Questionnaire') may be used to communicate the need for annual update.
        i. If no response after two (2) documented phone calls and 'CYSHCN Annual Eligibility' letter, mail

'CYSHCN Final Notice' letter. Close to the Special Formula program if no response to the 'CYSHCN Final Notice' letter. Allow a minimum of two (2) weeks for client response to letter(s).

4. Review acuity levels (Appendix 16) at least annually and amend as needed.
5. Provide transition services when indicated in accordance with the Transition Planning policy.
6. Order and dispense special formula per Appendix A: CYSHCN Special Formula Invoice Procedures and per provider's medical request (see Standard 4 for medical request requirements).
    a. Order up to **three-month supply** of approved formula (Do NOT order more than a three-month supply of formula).
    b. Dispense up to a three-month supply at one time (Do NOT dispense more than a three-month supply at any one time to ensure contact with the child/family and to determine continuing need).
7. Submit and log invoices in accordance with Appendix A: CYSHCN Special Formula Invoice Procedures.
8. Disposal of formula: If sites have CYSHCN formula on hand that will expire within a month, the procedure for disposal is: open can and pour out contents and dispose of container. Report this to the Regional Nurse Unit Manager.
9. Within **three months of the initial authorization**, document via a 'CYSHCN Note' (DPH 1619A), or if indicated via the 'CYSHCN Nutrition Assessment and Plan of Care: Infant and Child' Ad Hoc Form (DPH 1545), an interim summary regarding progress with the intervention plan. The summary must include: review of the feeding regimen with determination of continued appropriateness, review of updated anthropometrics if available, and progress with interventions/goals.
10. Complete via the 'CYSHCN Nutrition Assessment and Plan of Care: Infant and Child' Ad Hoc Form (DPH 1545) an updated **nutrition assessment every six months**, and more often if needed, based on child's medical needs and/or nutritional status to determine on-going need and amount of special formula to be authorized.
    a. If anthropometric measures within the last 60 days are available, create a new EHR growth chart (DPH 0774 or 0775).
11. Close the record and remove from caseload in accordance with the Documentation and Quality Assurance policy. If no services are requested over a 1-year period and there is a documented

need for the child to remain enrolled on the Special Formula program, consult with the CYSHCN CO Dietitian Consultant.

3. CYSHCN CO Dietitian Consultant (or CO designee) Responsibilities:
    a. Review Special Formula intake application for completeness, including: nutrition care process, supporting documentation, clinical and nutrition eligibility, and appropriate formula. Forward application, as indicated, to CYSHCN Medical Consultant for medical review/determination.
    b. Document application's determination (approval or denial) in client's electronic health record via 'CYSHCN Special Formula Disposition' Ad Hoc Form (DPH 4504), 'CYSHCN Note' (DPH 1619A), and the appropriate letter ('CYSHCN Special Formula Approval' or 'CYSHCN Special Formula Denial' letter). Notify the requesting CYSHCN Regional Dietitian and Nurse Unit Manager via electronic message, including copy of client letter for regional office to mail to parent/guardian via USPS.
    c. Track, log, and reconcile Special Formula orders and invoices for CYSHCN CO.

E. DATE OF APPROVAL/REVISION

Approved: 3/14/2014
Revision Dates: 12/5/2019, 3/15/202, 2/6/2023
Revision 12/11/2025:

- Transferred from Department of Health and Environmental Control (DHEC) to DPH.
- Added disclaimer of contract of employment.
- Revised throughout to reflect current EHR processes.
- Policy Statement added: Services of the Children and Youth with Special Health Care Needs (CYSHCN) Special Formula program are delivered by licensed dietitians (RD, RDN, LD) who conduct nutrition assessments, nutrition education/ counseling, care coordination, and provide ordered special formulas to enrolled clients.
- Added Section B. Definitions to define regular infant formula, special formula, and metabolic formula
- C. Standards 1. Eligibility Criteria. E. Clinical Criteria added: "includes diagnosis and ICD code documented by a licensed health care provider (physician, PA, or APRN)."
- C. Standards 1. Eligibility Criteria. F. Nutritional Criteria added "Note: All above-listed eligibility criteria (Standard 1.a-e) must be met before any Nutritional Criteria is considered."
- Added C. Standards 3-5.
- Added Section D. Procedures to capture current processes and delineated by responsible party (referring provider, CYSHCN Regional Office, and CYSHCN CO Dietitian Consultant).
- Added Appendix A: CYSHCN Special Formula Invoice Procedures