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ARCHIVES DIVISION

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 410
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

FILED

05/30/2024 10:08 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Clarify language and Division title, amend rules to include current criteria, reimbursement, and coverage guidelines.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 06/21/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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NEED FOR THE RULE(S)

Rule(s) Description of proposed changes

410-148-0000 Include EPSDT program rules as listed in conjunction with EPIV.

410-148-0020 Replacing DMAP reference to Division replaces, physician with practitioner to match federal Medicaid regulations, revising order requirements, clarifying type of assessment for ongoing services.

410-148-0060 Remove authorization of pumps, Consider adding "Must be identified as administered orally by use of "BO" modifier to table.

410-148-0080 Replacing DMAP reference to Division, removing PA requirement for IV infusion pumps and enteral formulae pumps.

410-148-0095 Repealing/Removing entire rule – client copayments no longer apply.

410-148-0100 Replacing DMAP reference to Division, adding medically appropriate language to enteral formula and parenteral formula with reference to meeting criteria in Ch.410-Div 148 OARs, and clarifying rule for no reimbursement regarding oral nutritional supplements that are in addition to consumption of food items or meals.

410-148-0260 Replacing DMAP reference to Division, revise language supporting most up-to-date information related

to formula/nutritional supplement

HCPCS codes and coding guidance for providers, adding language to clarify coverage, PA, & guidelines for human donor milk (refer to HERC GN), added oral thickener guidelines, applied EPSDT in terms of adults/children/youth & amended language/coverage accordingly, added inborn errors of metabolism and oral aversion to criteria for adults/children/youth, added supply language to clarify HCPCS codes, units of service to include instructions for initial delivery of new formula and refill requirements on a recurring basis, added references to medically necessary and medically appropriate for both adults & children/youth, amended language format for when a new prescription is required, & removal of listed procedure codes because those will be included in the new OAR table.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

EPIV Provider Guide on EPIV Program Page, HERC Guideline Note 183, LCD- L38955 Enteral Nutrition, LCA- A58833 Enteral Nutrition-Policy Article, EPSDT Division Rules, PDAC, 7 CFR 246.10,

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

We do not anticipate any positive or negative effects to racial equity.

FISCAL AND ECONOMIC IMPACT:

We do not expect these revisions to have a fiscal impact for the Oregon Health Plan. Oral formula, nutritional supplements, equipment, and supplies are included in the budget for OHP. For OHP recipients, there will be no change in financial impact or cost for oral formula, nutritional supplements, equipment, or supplies. The 60-day supply at the initial formula dispensing may result in some increase in wasted, unused products which would be a slight increase in costs.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) These revisions are expected to impact FFS, CCO's, the WIC program & member's enrolled in OHP FFS/CCO's who also participate in the WIC program, DME Providers, DME Suppliers, oral formula manufacturers, and prescribing provider networks.

(2)

(a) There is an unknown number of small businesses who are supplying EPIV products to Oregon FFS participants and these rule proposals would not affect the number of small businesses participating in FFS.

(b) For small businesses, this amendment does not change any of these activities required. After this rule is filed, these burdens are anticipated to remain the same.

(c) We do not anticipate any changes for small businesses as small businesses will not have to purchase any new supplies or equipment because of these revisions.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were solicited through invitation to both the Pre-RAC listening sessions as well as invited to

participate in the RAC.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

410-148-0000, 410-148-0020, 410-148-0060, 410-148-0080, 410-148-0095, 410-148-0100, 410-148-0260

AMEND: 410-148-0000

RULE SUMMARY: Include EPSDT program rules as listed in conjunction with EPIV.

CHANGES TO RULE:

410-148-0000

Foreword ¶¶

(1) The Home Enteral/Parenteral Nutrition and IV Services rules are a user's manual designed to assist providers in preparing health claims for medical assistance program clients. The Home Enteral/Parenteral Nutrition and IV Services provider rules are to be used in conjunction with the General Rules for Oregon Medical Assistance Programs, the Oregon Health Plan administrative rules, the Pharmaceutical Services administrative rules, the Early and Periodic Screening, Diagnostic and Treatment administrative rules, and other relevant provider rules and supplemental information.¶¶

(2) The Home Enteral/Parenteral Nutrition and IV Services provider rules include procedure codes with restrictions, and limitations. The Home EPIV code and fee schedule, which is not a part of these rules, is not an exhaustive list of OHP covered service codes. Please consult the Prioritized List of Health Services for the Oregon Health Plan and the Division's Maximum Allowable Table.¶¶

(3) The Division endeavors to furnish medical providers with up-to-date billing, procedural information, and guidelines to keep pace with program changes and governmental requirements.¶¶

(4) Providers should always follow the Division administrative rules in effect on the date of service.¶¶

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 413.042

Statutes/Other Implemented: ORS 414.065

AMEND: 410-148-0020

RULE SUMMARY: Replacing DMAP reference to Division replaces, physician with practitioner to match federal Medicaid regulations, revising order requirements, clarifying type of assessment for ongoing services.

CHANGES TO RULE:

410-148-0020

Home Enteral/Parenteral Nutrition and IV Services ¶

(1) ~~The Division of Medical Assistance Programs (Division) will~~ shall make payment for medically appropriate and medically necessary goods, supplies, and services for home enteral/parenteral nutrition and IV therapy on written order or prescription. ¶

(a) ~~The order or prescription must be dated and signed by a licensed prescribing practitioner. The order shall be legible and specify the service required, the ICD-10-CM diagnosis codes, number of (s), the route of administration, the amounts and prescribed, and the length of time needed.~~ ¶

(b) ~~The prescription or written physician order for solutions and medications~~ practitioner's order must be retained on file by the provider of service for the period of time specified in the Division's General Rules. ¶

(c) ~~An annual nutritional assessment performed by a registered dietitian, or the treating practitioner~~ and a new prescription are required once a year for ongoing services. ¶

(d) Also covered are services for subcutaneous, epidural and intrathecal injections requiring pump or gravity delivery. ¶

(2) All claims for enteral/parenteral nutrition and IV services require a valid ICD-10-CM diagnosis code. It is the provider's responsibility to obtain the actual diagnosis code(s) from the prescribing practitioner. Reimbursement will be made according to covered services on funded lines of the Health Services Commission's Prioritized List of Health Services, and these rules. ¶

(3) ~~The Division requires~~ shall cover one initial nursing service visit to assess the home environment and appropriateness of enteral/parenteral nutrition or IV services in the home setting ~~and to establish the client's treatment plan.~~ ¶

~~(a) This nursing service visit for assessment purposes does not require payment authorization.~~ ¶

~~(b) The nursing service assessment visit is not required when:~~ ¶

~~(A) The only service provided is oral nutritional supplementation;~~ ¶

~~(B) The services are performed in an Ambulatory Infusion Suite of the home infusion therapy provider when recommended by the treating practitioner to establish the client's treatment plan.~~ ¶

(4) Nursing service visits specific to this Home Enteral/Parenteral and IV services program are provided in the home, or an Ambulatory Infusion Suite of the Home Infusion Therapy Provider (AIS) and ~~will~~ shall be reimbursed by the Division only when prior authorized, and performed by a person who is licensed by the Oregon State Board of Nursing to practice as a Registered Nurse. All registered nurse delegated or assigned nursing care tasks must comply with the Oregon State Board of Nursing, Nurse Practitioner Act and Administrative Rules regulating the practice of nursing. ¶

(5) Payment for services identified in the Home Enteral/Parenteral Nutrition and IV Services provider rules ~~will~~ shall be made only when provided in the client's place of residence (i.e., home or nursing facility) or an Ambulatory Infusion Suite (AIS).

Statutory/Other Authority: ORS 413.042

Statutes/Other Implemented: ORS 414.065

AMEND: 410-148-0060

RULE SUMMARY: Possibly add definitions for "Payment Authorization" and "Prior Authorization", Consider adding "Must be identified as administered orally by use of "BO" modifier

CHANGES TO RULE:

410-148-0060

Authorization ¶¶

(1) ~~The Division of Medical Assistance Programs (Division)~~ requires authorization of payment for the following items or services:¶¶

(a) ~~All enteral/parenteral or IV infusion pumps. The provider is required to submit documentation with each request proving that other (non-pump) methods of delivery do not meet the client's medical need;~~¶¶

~~(b) All nursing service visits, except the assessment nursing visit, associated with home enteral/parenteral nutrition or IV services;~~¶¶

~~(e) All oral formula and nutritional supplements;~~¶¶

~~(c) Human Donor Milk;~~¶¶

(d) All drugs and goods identified as requiring payment authorization in the Pharmaceutical Services administrative rules (chapter 410, division 121). Contact the Division's Pharmacy Benefit Manager to determine those items that require prior authorization.¶¶

(2) The Division ~~wishall~~ approve payment for the above home enteral/parenteral nutrition and/or IV services entities when they are considered to be "medically appropriate." Division administrative rules are met, and services are medically appropriate and medically necessary as defined in OAR 410-120-0000 for clients aged 21 and older and OAR 410-151-0001 for clients under the age of 21; ¶¶

(3) The Division requires authorization of payment for those services that require authorization even though the client has other insurance that may cover the service. Authorization of payment is not required for Medicare covered services.¶¶

(4) For services requiring authorization, providers must contact the Division's Medical Unit for authorization within five (5) working days following initiation of services. Authorization ~~wishall~~ be given based on medical appropriateness, appropriateness of level of care given, cost and/or effectiveness.¶¶

(5) How to obtain payment authorization:¶¶

(a) The Division's Medical Unit is responsible for authorization for services for clients identified as Medically Fragile Children's Unit clients;¶¶

(b) Contact the Division's Pharmacy Benefit Manager, prior authorization help desk to request oral nutrition supplements;¶¶

(c) Contact the Division's Medical Unit to request all other authorization;¶¶

(d) Payment authorization does not guarantee reimbursement.¶¶

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 413.042

Statutes/Other Implemented: ORS 414.065

AMEND: 410-148-0080

RULE SUMMARY: Replacing DMAP reference to Division, removing PA requirement for IV infusion pumps and enteral formulae pumps.

CHANGES TO RULE:

410-148-0080

Equipment Rental/Purchase/Repair ¶

(1) The following equipment shall be ~~authorized~~covered, if medically appropriate and when cost effective, on a rental basis only:¶

(a) IV infusion pumps;¶

(b) Enteral formulae pumps.¶

(2) The equipment provider is responsible for providing working equipment including replacement if repairs are necessary.¶

(3) Pump rental payment ~~wishall~~ not be made beyond the purchase price, ~~but no more than 15 consecutive months when the period of use extends beyond or beyond fifteen (15) consecutive months;~~¶

(a) Consecutive months are defined as "any period of continuous use where no more than a 60-day break occurs";¶

(b) ~~The Division of Medical Assistance Programs (Division) shall consider that the maximum rental period the pump paid in full and toward purchase price is --ned by the client following fifteen (15) consecutive rental months of pump rental. Tr when the purchase price has been met at the earlier of the purchase price or 15 consecutive months; of the pump is met (whichever is least costly);~~¶

(c) Having met the purchase price as described in this rule, the pump becomes property of the client, and the patient is responsible for all maintenance and repairs.¶

(A) The Division can still allow for medically necessary repairs on equipment that the patient owns.¶

(B) The provider may bill the Division for maintenance and servicing of the pump (as long as that maintenance and servicing is not covered under any manufacturer/supplier warranty) when a period of at least six (6) months has elapsed since the final month of pump rental. Payment for the maintenance service ~~wishall~~ only be made one time during every six- (6) month period.¶

(C) For a purchased pump, a rental pump may be ~~prior authorized~~covered for up to one (1) month during equipment repair for a client requiring medically necessary, continuous service.¶

(D) Reasonable useful lifetime of a pump is no less than eight (8) years. Computation of the useful lifetime is based on the date the pump was purchased for the client, not the age of the pump.¶

(4) All other equipment for home enteral/parenteral nutrition and IV services ~~wishall~~ be ~~authorized~~covered as either purchase or based on length of need and medical appropriateness.¶

(5) All rental or purchase of equipment, full services warranty, pickup, delivery, set-up, fitting and adjustments are included in the reimbursement. Individual consideration may be given in specific circumstances upon written request to the Division.¶

(6) Repair of rental equipment is the responsibility of the provider.¶

(7) The Division ~~wishall~~ not make payment for rental of pumps that are supplied by any manufacturer at no cost to the provider.

Statutory/Other Authority: ORS 413.042

Statutes/Other Implemented: ORS 414.065

REPEAL: 410-148-0095

RULE SUMMARY: Repealing/Removing entire rule – client copayments no longer apply.

CHANGES TO RULE:

~~410-148-0095~~

~~Client Copayments~~

~~Copayments may be required for non-American Indian/Alaska Native clients for certain services. See OAR 410-120-1230 for specific details.~~

~~Statutory/Other Authority: ORS 413.042~~

~~Statutes/Other Implemented: ORS 414.065~~

AMEND: 410-148-0100

RULE SUMMARY: Replacing DMAP reference to Division, adding medically appropriate language to enteral formula and parenteral formula with reference to meeting criteria in Ch.410-Div 148 OARs, and clarifying rule for no reimbursement regarding oral nutritional supplements that are in addition to consumption of food items or meals.

CHANGES TO RULE:

410-148-0100

Reimbursement ¶

(1) Drug ingredients (medications) shall be reimbursed as defined in the Division of ~~Medical Assistance Programs (Division)~~ Pharmaceutical Services administrative rules (~~eChapter 410, dDivision 121~~).¶

(2) The following service/goods ~~wish~~ shall be reimbursed on a fee-for-service basis according to the Division EPIV Fee Schedule found in the Home Enteral/Parenteral Nutrition and IV Services on the Division website:¶

(a) Enteral formula;¶

~~(b) Oral nutritional supplements which are medically appropriate and meet the criteria specified in 410-148-0260;¶~~

(b) Parenteral nutrition solution which is medically appropriate and meets the criteria specified in Chapter 410, Division 148 administrative rules;¶

(b) Oral nutritional supplements which are medically appropriate and meet the criteria specified in Chapter 410, Division 148 administrative rules;¶

(c) Parenteral nutrition solutions which are medically appropriate and meet the criteria specified in Chapter 410, Division 148 administrative rules;¶

(3) Reimbursement for services ~~wish~~ shall be based on the lesser of the amount billed, or the Division maximum allowable rate. When the service is covered by Medicare, reimbursement ~~wish~~ shall be based on the lesser of the amount billed, Medicare's allowed amount, or the Division maximum allowable rate.¶

(4) Reimbursement for supplies that require authorization or services/supplies that are listed as Not Otherwise Classified (NOC) or By Report (BR) must be billed to the Division at the providers' acquisition cost; and ~~wish~~ shall be reimbursed at such rate.¶

(a) For purposes of this rule, Acquisition Cost is defined as the actual dollar amount paid by the provider to purchase the item directly from the manufacturer (or supplier) plus any shipping and/or postage for the item. Submit documentation identifying acquisition cost with your authorization request;¶

(b) Per diem, as it relates to reimbursement, represents each day that a given patient is provided access to a prescribed therapy. This definition is valid for per diem therapies of up to and including every 72 hours.¶

(c) Per diem reimbursement includes, but is not limited to:¶

(A) Professional pharmacy services:¶

(i) Initial and ongoing assessment/clinical monitoring;¶

(ii) Coordination with medical professionals, family and other caregivers;¶

(iii) Sterile procedures, including IV admixtures, clean room upkeep and all biomedical procedures necessary for a safe environment;¶

(iv) Compounding of medication/medication set-up.¶

(B) Infusion therapy related supplies:¶

(i) Durable, reusable or elastomeric disposable infusion pumps;¶

(ii) All infusion or other administration devices;¶

(iii) Short peripheral vascular access devices;¶

(iv) Needles, gauze, sterile tubing, catheters, dressing kits, and other supplies necessary for the safe and effective administration of infusion therapy.¶

(C) Comprehensive, 24-hour per day, seven (7) days per week delivery and pickup services (includes mileage).¶

(5) Reimbursement ~~wish~~ shall not be made for the following:¶

(a) Central catheter insertion or transfusion of blood/blood products in the client's home;¶

(b) Central catheter insertion in the nursing facility;¶

(c) Intradialytic parenteral nutrition in the client's home or Nursing Facility;¶

~~(d) Oral infant formula that nutritional supplements when the client is available through the Women's, Infant and Children (WIC) program;¶~~

(e) Oral nutritional supplements that are in addition to ~~be~~ to meet recommended caloric/protein and micronutrient intake through the consumption of food items or meals;¶

~~(f) Tocolytic pumps for pre-term labor management;¶~~

~~(g) Home enteral/parenteral nutrition or IV services outside of the client's place of residence (i.e. home, nursing~~

facility or AIS).¶

(6) The Oregon Health Plan (OHP) shall be primary payer, before the Women's, Infant and Children (WIC) program, for all formula covered by OHP to treat those infants and children who are enrolled in both OHP and participating in the WIC program.

Statutory/Other Authority: ORS 413.042

Statutes/Other Implemented: ORS 414.065

RULE SUMMARY: Replacing DMAP reference to Division, revise language supporting most up-to-date information related to formula/nutritional supplement HCPCS codes and coding guidance for providers, adding language to clarify coverage, PA, & guidelines for human donor milk (refer to HERC GN), added oral thickener guidelines, applied EPSDT in terms of adults/children/youth & amended language/coverage accordingly, added inborn errors of metabolism and oral aversion to criteria for adults/children/youth, added supply language to clarify HCPCS codes, units of service to include instructions for initial delivery of new formula and refill requirements on a recurring basis, added references to medically necessary and medically appropriate for both adults & children/youth, amended language format for when a new prescription is required, & removal of listed procedure codes because those will be included in the new OAR table.

CHANGES TO RULE:

410-148-0260

Home-Enteral Nutrition and Oral Nutritional Supplements ¶

(1) Codes that have "PA" indicated require prior authorization. Codes with BR indicated are covered by report. Indications and limitations of coverage and medical appropriateness: The Division may cover home enteral formula, oral nutritional supplements, equipment, supplies, and services for clients of any age. Refer to Table 148-0260-1 and the following guidelines: ¶

(2a) Enteral nutrition formula. User refers to nutritional formula administered by tube or orally fed into the gastrointestinal tract (HCPCS codes may include, but are not limited to, B415049 through B4156 when billing for tube fed nutritional formulae. If the product dispensed is not shown in 62). Depending on the route of administration, additional equipment and supplies may be covered: ¶

(b) Blenderized enteral formula, whether administered by tube or orally fed, describes formulas containing natural foods that are blenderized and packaged by a manufacturer. Code B4149 must not be used for foods that have been blenderized by the beneficiary or caregiver: ¶

(c) Refer to the product classification list on the Medicare Pricing, Data Analysis and Coding (PDAC) contractor website for appropriate Healthcare Common Procedure Coding System (HCPCS) code description, select a category equivalent when billing the Division of Medical Assistance Programs (Division): assigned to formula, supplements, equipment, and supplies: ¶

(d) If the formula, item, or supply is not listed on the PDAC contractor website, the provider must contact the PDAC contractor for a coding determination. The Medicare Pricing, Data Analysis and Coding contractor is responsible for assisting DMEPOS providers and manufacturers in determining which HCPCS code shall be used to describe DMEPOS items: ¶

(32) Oral enteral formula and nutritional supplements administered orally: ¶

(a) Prior authorization is required on all: ¶

(b) Enteral formula and oral nutritional supplements documented as the primary source of nutrition, for a client of any age, meets criteria for expedited prior authorization review: ¶

(bc) Oral nutritional formula and supplements can may be billed through the on-line point of sale pharmacy system, or by paper using the CMS-1500 claim form or the electronic 837P claim form. Use the product's National Drug Code (NDC) and Healthcare Common Procedure Coding System (HCPC) code when billing that approved when the following criteria has been met: ¶

(A) For Adults 21 years of age and older: ¶

(i) An assessment performed by a registered dietitian or treating practitioner, at onset and annually thereafter, documenting the client is unable to meet their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form; and ¶

(ii) Documentation showing the prescribed oral nutritional formula and/or nutritional supplements are an integral part of treatment for a nutritional deficiency as identified by one of the following conditions: ¶

(I) Prolonged history (e.g., years) of malnutrition; or ¶

(II) Documentation of weight, either currently or historically, supported by oral nutritional supplements; or ¶

(III) Increased metabolic need resulting from severe trauma; or ¶

(IV) Malabsorption difficulties (e.g., short-gut syndrome, fistula, cystic fibrosis, renal dialysis); or ¶

(V) Inborn errors of metabolism (e.g., fructose intolerance, galactosemia, maple syrup urine disease C(MS-1500 or electronic 837P claim form; ¶

(e) If UD), or phenylketonuria (PKU); or ¶

(VI) Ongoing cancer treatment, advanced Acquired Immune Deficiency Syndrome (AIDS) or pulmonary insufficiency; or ¶

(VII) Oral aversion or other product dispensed is not shown in one of the listed categories, select a category that is equivalent when billing the Division;

(d) Oral nutritional supplements may be approved when the following criteria has been met:

(A) Clients age 6 and above:

(i) Must have a psychological condition making it difficult for a client to consume their recommended caloric/protein or micronutrient needs through regular, liquified, blenderized, or pureed foods in any modified texture or form;

(B) For Children and Youth under the age of 21. An assessment performed by a registered dietitian or treating practitioner, at onset and annually thereafter, documenting the prescribed nutritional formula and/or nutritional supplementation is medically necessary and appropriate as an integral part of treatment for any condition noted above or for the prevention of nutritional deficiency or malnutrition as identified by one of the following:

(I) Recent low serum protein levels; or

(II) Recent registered dietician assessment shows sufficient caloric/protein intake is not obtainable Documentation showing the client is unable to meet their recommended caloric/protein or micronutrient needs through regular, liquefied, blenderized, or pureed foods;

(ii) The clinical exception to in any modified texture or form; or

(ii) Malabsorption or other diagnosed medical condition which involves dietary restriction as part of the requirements of (I) and (II) must meet the following at treatment, including but not limited to food allergy, Eosinophilic disorders (EoE), Food Protein Induced Enterocolitis (FPIES);

(3) Enteral formula administered by tube for a client of any age:

(I) Prolonged history (i.e. years) of malnutrition, and diagnosis or symptoms of cachexia, and

(II) Client residence in home, nursing facility, or chronic home care facility, and

(III) Enteral nutrition is covered for a client of any age who requires feedings via an enteral access device (tube) to provide sufficient nutrients to maintain weight and strength otherwise not possible by dietary adjustment and/or oral supplements;

(b) Supplies:

(A) The unit of service for the supply allowance (B4034, B4035, B4036, or B4148) is one (1) per day;

(i) Enteral feeding supply kit allowances (B4034, B4035, B4036, and B4148), are all-inclusive, with the exception of B4105 in-line digestive enzyme cartridge. Two in-line digestive enzyme cartridges (B4105) per day is considered reasonable and necessary;

(ii) Where (I) and (II) would be futile and invasive

(iii) Must have a recent unplanned weight loss of at least 10%, plus one of the following: feeding supply allowance (B4034, B4035, B4036, and B4148) must correspond with the method of enteral nutrition administration (syringe, pump, gravity, elastomeric control fed);

(I) The daily supply allowances include, but are not limited to, a catheter/tube anchoring device, feeding bag/container, flushing solution bag/container, administration set tubing, extension tubing, feeding/flushing syringes, gastrostomy tube holder, dressings (any type) used for gastrostomy tube site, tape (to secure tube or dressings), Y connector, adapter, gastric pressure relief valve, declogging device;

(II) Increased metabolic need resulting from severe trauma; or

(II) Malabsorption difficulties (e.g., short-gut syndrome, fistula, cystic fibrosis) must be included within the daily supply allowance must not be separately billed using the miscellaneous code (B9998), or using a specific code for any individual item;

(B) Three nasogastric tubes (B4081, B4082, and B4083), or one gastrostomy/jejunostomy tube (B4087 or B4088) every three (3) months is considered reasonable and necessary. For those clients requiring more frequent changes or replacement of a non-functional tube, prior authorization is; renal dialysis); or

(III) Ongoing cancer treatment, advanced Acquired Immune Deficiency Syndrome (AIDS) or pulmonary insufficiency;

(iv) Weight loss criteria may be waived if body weight is being maintained by supplements due to patient's medical condition (e.g., renal failure, AIDS) required and there must be documentation to support the need;

(C) For children and youth under the age of 21, a back-up gastrostomy/jejunostomy tube (B4087 or B4088) may be covered when prescribed;

(4) Initial delivery of each enteral formula, oral supplement, equipment, and supplies. For each new formula or supplement prescribed, suppliers shall provide a 60-day supply, unless the prescriber recommends less than a 60-day supply, regardless of which delivery method is utilized. The prescribed length of need must exceed sixty (60) days for this rule to apply;

(5) Refill requirements for formula items and supplies provided on a recurring basis:

(a) For all formulas, nutritional supplements, and supplies that are provided on a recurring basis as refills to the original order, suppliers are required to have contact with the client or designee either by call, text, or email prior to dispensing to confirm any changes or modifications to the order;

(b) Contact with the client or designee regarding refills shall take place no less than 35 calendar days prior to the

end of usage for the current product and the next scheduled delivery/shipping date;¶

(c) For delivery or shipment of refills, the supplier shall dispense the formula and supplies no less than 30 calendar days prior to the end of usage for the current product regardless of which delivery method is utilized;¶

(BA) Clients under age 6;¶

(i) Diagnosis of failure to thrive Regardless of utilization, a supplier must not dispense more than a 1-month quantity of formula or supplies on a recurring basis;¶

(B) Automatic shipments on a pre-determined basis, even if authorized by the client or designee, are not allowed;¶

(ii) Must meet same criteria as above, with the exception of % of weight loss. C) Suppliers may dispense more than a 1-month quantity of formula or supplies only on a periodic basis to ensure continuation of care during times of travel or when the client is away from the home for an extended period of days. Documentation of the reason for the additional quantity, client's travel or time away from home, shall be kept on file with the supplier and made available to the Division upon request. ¶

(46) Enteral nutrition equipment;¶

(a) All repair and maintenance is are subject to rule OAR 410-1480-0080;¶

(b) Procedure codes Food thickener (B4100) administered orally;¶

(Aa) S5036, Repair of infusion device (each 15 minutes = 1 unit) - PA;¶

(B) B9998, Enteral nutrition infusion pump replacement parts will be reimbursed at provider's acquisition cost (including shipping and handling);¶

(C) B9000, Enteral nutrition infusion pump, without alarm - rental (1 month = 1 unit) - PA; A thickener is an additive that decreases the flow rate of thin liquids. A thickener may be covered when prescribed for a client of any age who has participated in a swallowing evaluation or study and for the treatment of a swallowing disorder resulting from one of the following: ¶

(A) A diagnosis of dysphagia which negatively impacts the ability to swallow; or ¶

(B) Chronic diseases such as, but not limited to, Parkinson's, dementia, reflux disease, stroke, and spinal cord injury; or ¶

(C) Treatment of head, neck, or throat cancer; or ¶

(D) Documented aspiration of food or liquid associated with chronic illness or disease. ¶

(b) Annual follow up with treating practitioner is required to ensure the food thickener remains reasonable and necessary and to confirm any changes or modifications to the order. ¶

(8) Human donor milk;¶

(Da) B9002, Enteral nutrition infusion pump, with alarm - rental (1 month = 1 unit) - PA;¶

(E) E0776, IV pole - purchase; Refer to the Prioritized List Guideline Note for coverage guidelines;¶

(b) Prior authorization is required;¶

(9) Procedure codes;¶

(a) Refer to Table 148-0260-1;¶

(b) Codes that have "PA" indicated require prior authorization;¶

(10) Billing instructions: ¶

(Fa) E0776, modifier RR, IV pole - rental (1 day = 1 unit) The allowance for all items includes delivery regardless of which delivery method is utilized;¶

(Gb) S9342, Enteral nutrition via pump (1 day = 1 unit) - PA. ¶

(5) Home infusion therapy;¶

(a) S9325, Home infusion, pain management (do not use with code S9326, S9327 or S9328) - PA ¶

(b) S9326, Home infusion, continuous pain management - PA;¶

(c) S9327, Home infusion, intermittent pain management - PA;¶

(d) S9328, Home infusion, implanted pump pain management - PA. Oral formula and/or nutritional supplements can be billed through the on-line point of sale pharmacy system, or by paper using the CMS 1500 claim form or the electronic 837P claim form. Use the product's National Drug Code (NDC) and Healthcare Common Procedure Coding System (HCPCS) code when billing the CMS 1500 or electronic 837P claim form;¶

(11) Documentation requirements: ¶

(a) The purchase, rental, or repair of durable medical equipment and the purchase of supplies must have an order from the prescribing practitioner prior to dispensing items to a client;¶

(b) A new prescription is required when: there is a change in the item(s), frequency of use, amount prescribed, a change in the length of need, or a previously established length of need expires. A new prescription is required annually;¶

(c) For services requiring prior authorization (PA), submit documentation that supports coverage criteria in this rule are met;¶

(d) All nutritional formula, equipment, supplies, and services shall be documented as medically appropriate and medically necessary by the registered dietitian and/or treating practitioner;¶

(6A) Not Otherwise Classified (NOC): "Medically Appropriate" has the meaning given that term in OAR 410-120-

~~0000 for clients 21 years of age and older, and OAR 410-151-0001 for clients under the age of 21;¶
(aB) B9998, NOC for enteral supplies "Medically Necessary" has the meaning given that term in OAR 410-120-0000 for clients 21 years of age and older, and OAR 410-151-0001 for clients under the age of 21;¶
(be) S9379, Home infusion therapy, NOC - PA/BR Documentation that coverage criteria have been met must be present in the client's medical records. These records shall be kept on file with the DME provider and made available to the Division on request.~~

Statutory/Other Authority: ORS 413.042

Statutes/Other Implemented: ORS 414.065

RULE ATTACHMENTS MAY NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Table 122-0260-1 Enteral Nutrition, Oral Supplements, Equipment, & Supplies

***All formula and supplements administered orally require prior authorization and BO modifier.**

Code	Description	PA	PC	RT	MR	RP	NF
A9270	NON-COVERED ITEM OR SERVICE	PA					
B4034	ENTERAL FEEDING SUPPLY KIT; SYRINGE FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE - Unit of service (UOS) is one (1) UOS per day.		PC				
B4035	ENTERAL FEEDING SUPPLY KIT; PUMP FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE - Unit of service (UOS) is one (1) UOS per day.		PC				
B4036	ENTERAL FEEDING SUPPLY KIT; GRAVITY FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE - Unit of service (UOS) is one (1) UOS per day.		PC				
B4081	NASOGASTRIC TUBING WITH STYLET - Limited to 1ea per month		PC				
B4082	NASOGASTRIC TUBING WITHOUT STYLET - Limited to 1ea per month		PC				
B4083	STOMACH TUBE - LEVINE TYPE - Limited to 1ea per month		PC				

Code	Description	PA	PC	RT	MR	RP	NF
B4087	GASTROSTOMY/JEJUNOSTOMY TUBE, STANDARD, ANY MATERIAL, ANY TYPE, EACH - Limited to 1ea every 3 months		PC				
B4088	GASTROSTOMY/JEJUNOSTOMY TUBE, LOW-PROFILE, ANY MATERIAL, ANY TYPE, EACH - Limited to 1ea every 3 months		PC				
B4100	FOOD THICKENER, ADMINISTERED ORALLY, - 1 unit = 1 ounce		PC				
B4104	ADDITIVE FOR ENTERAL FORMULA (E.G., FIBER) Note: Enteral formula codes include all nutrients including vitamins, minerals, and fiber; therefore, this code may be considered bundled if requested separately.	*	PC				
B4105	IN-LINE CARTRIDGE CONTAINING DIGESTIVE ENZYME(S) FOR ENTERAL FEEDING, EACH - Limited to 2ea per day		PC				
B4148	ENTERAL FEEDING SUPPLY KIT; ELASTOMERIC CONTROL FED, PER DAY, INCLUDES BUT NOT LIMITED TO FEEDING/FLUSHING SYRINGE, ADMINISTRATION SET TUBING, DRESSINGS, TAPE - Unit of service (UOS) is one (1) UOS per day.		PC				
B4149	ENTERAL FORMULA, MANUFACTURED BLENDERIZED NATURAL FOODS WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED	*	PC				

Code	Description	PA	PC	RT	MR	RP	NF
	THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit						
B4150	ENTERAL FORMULA, NUTRITIONALLY COMPLETE WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				
B4152	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, CALORICALLY DENSE (EQUAL TO OR GREATER THAN 1.5 KCAL/ML) WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				
B4153	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, HYDROLYZED PROTEINS (AMINO ACIDS AND PEPTIDE CHAIN), INCLUDES FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				
B4154	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, FOR SPECIAL METABOLIC NEEDS, EXCLUDES INHERITED DISEASE OF METABOLISM, INCLUDES ALTERED COMPOSITION OF PROTEINS, FATS, CARBOHYDRATES,	*	PC				

Code	Description	PA	PC	RT	MR	RP	NF
	VITAMINS AND/OR MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit						
B4155	ENTERAL FORMULA, NUTRITIONALLY INCOMPLETE/MODULAR NUTRIENTS, INCLUDES SPECIFIC NUTRIENTS, CARBOHYDRATES (E.G., GLUCOSE POLYMERS), PROTEINS/AMINO ACIDS (E.G., GLUTAMINE, ARGININE), FAT (E.G., MEDIUM CHAIN TRIGLYCERIDES) OR COMBINATION, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				
B4157	ENTERAL FORMULA, NUTRITIONALLY COMPLETE, FOR SPECIAL METABOLIC NEEDS FOR INHERITED DISEASE OF METABOLISM, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				
B4158	ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER AND/OR IRON, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				
B4159	ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY	*	PC				

Code	Description	PA	PC	RT	MR	RP	NF
	COMPLETE SOY BASED WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER AND/OR IRON, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit						
B4160	ENTERAL FORMULA, FOR PEDIATRICS, NUTRITIONALLY COMPLETE CALORICALLY DENSE (EQUAL TO OR GREATER THAN 0.7 KCAL/ML) WITH INTACT NUTRIENTS, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				
B4161	ENTERAL FORMULA, FOR PEDIATRICS, HYDROLYZED/AMINO ACIDS AND PEPTIDE CHAIN PROTEINS, INCLUDES FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				
B4162	ENTERAL FORMULA, FOR PEDIATRICS, SPECIAL METABOLIC NEEDS FOR INHERITED DISEASE OF METABOLISM, INCLUDES PROTEINS, FATS, CARBOHYDRATES, VITAMINS AND MINERALS, MAY INCLUDE FIBER, ADMINISTERED THROUGH AN ENTERAL FEEDING TUBE, - 100 calories = 1 unit	*	PC				

Code	Description	PA	PC	RT	MR	RP	NF
B9002	ENTERAL NUTRITION INFUSION PUMP, ANY TYPE - 1 month = 1 unit - RUL = 8yrs			RT	15	RP	
B9998	NOC FOR ENTERAL SUPPLIES	PA	PC				
E0776	IV POLE - 1 month = 1 unit		PC	RT			

Code	Description	PA	PC	RT	MR	RP	NF
T2101	HUMAN DONOR MILK - 1 fluid ounce (oz) = 1 unit	PA	PC				
A4287	DISPOSABLE COLLECTION AND STORAGE BAG FOR BREAST MILK, ANY SIZE, ANY TYPE, EACH		PC				

Code	Description	PA	PC	RT	MR	RP	NF
S9341	HOME THERAPY; ENTERAL NUTRITION VIA GRAVITY; ADMINISTRATIVE SERVICES, PROFESSIONAL PHARMACY SERVICES, CARE COORDINATION, AND ALL NECESSARY SUPPLIES AND EQUIPMENT (ENTERAL FORMULA AND NURSING VISITS CODED SEPARATELY), PER DIEM - Unit of service (UOS) is one (1) UOS per day.						
S9342	HOME THERAPY; ENTERAL NUTRITION VIA PUMP; ADMINISTRATIVE SERVICES, PROFESSIONAL PHARMACY SERVICES, CARE COORDINATION, AND ALL NECESSARY SUPPLIES AND EQUIPMENT (ENTERAL FORMULA AND NURSING VISITS CODED SEPARATELY), PER DIEM - Unit of service (UOS) is one (1) UOS per day.		PC				

Code	Description	PA	PC	RT	MR	RP	NF
S9343	HOME THERAPY; ENTERAL NUTRITION VIA BOLUS; ADMINISTRATIVE SERVICES, PROFESSIONAL PHARMACY SERVICES, CARE COORDINATION, AND ALL NECESSARY SUPPLIES AND EQUIPMENT (ENTERAL FORMULA AND NURSING VISITS CODED SEPARATELY), PER DIEM - Unit of service (UOS) is one (1) UOS per day.		PC				
S9435	MEDICAL FOODS FOR INBORN ERRORS OF METABOLISM		PC				