City of Bellevue

Human Resources Department

Date: **June 2, 2016**

To: **LEOFF 1 Disability Board members**

From: **Paula Dillon x 7198, Human Resources**

RE: **Tuesday, June 7, 2016 Regular Meeting**

Please review the attached Agenda packet for the upcoming LEOFF 1 Disability Board meeting on Tuesday, June 7, 2016. The meeting will be held in Room 1E-118 at Bellevue City Hall, 450 110th Avenue NE, Bellevue WA 98004.

Attachments (**Please note that this Agenda Packet contains an Agenda Memo with extensive materials attached related to a special claim.)**

Distribution List

Disability Board Members:

Susan Neiman, Chair
Lynne Robinson, Councilmember
Vandana Slatter, Councilmember
Wayne Bergeron, Fire Department
Bryan Reil, Police Department

Other Copies:

Siona Windsor, City Attorney's Office
Kerry Sievers/Julie Howe, Human Resources
Paula Dillon, Human Resources
Sandra Nunnelee, Council Coordinator
Michelle Luce, Council Coordinator
Mark Risen, Fire Department
Steve Mylett, Police Department
Michelle Cash, Minutes taker – without attachments

City of Bellevue

Disability Board

Agenda Regular Meeting
City Hall, Conference Room 1E-118

Date: Tuesday, June 7, 2016

Time: 5:30 pm Administrative Meeting
6:00 pm Business Meeting

I. Call to Order

II. Roll Call

III. Public Comment

IV. Approval of Minutes of Regular Meetings, April 5 & May 3, 2016

V. Consideration of Applications for Disability Allowances

A. Applications for Disability Allowances
1) Fire Department

B. Applications for Disability Allowances Greater than 1 month
1) Fire Department

VII. Consideration of Medical Claims

A. Routine claims
B. Special claims
1. Medical Foods
C. Pre-Approved Recurring Long-Term Care Claims

VI. Staff Reports

VII. New Business

XI. Unfinished Business

X. Announce Date & Time of next meeting: Tuesday, July 5, 2016

XI. Adjournment

CITY OF BELLEVUE
LEOFF 1 DISABILITY BOARD
Meeting Minutes

April 5, 2016
5:30 p.m. – Administration
6:00 p.m. – Business Meeting

Conference Room 1E-118
Bellevue City Hall

MEMBERS PRESENT:	Chairperson Susan Neiman Boardmember Wayne Bergeron Boardmember Bryan Reil Councilmember Lynne Robinson
MEMBER ABSENT:	Councilmember Vandana Slatter
OTHERS PRESENT:	Paula Dillon, Human Resources Siona Windsor, City Attorney's Office
MINUTES TAKER:	Michelle Cash

I. CALL TO ORDER

The meeting was called to order at 6:04 p.m. by Chair Neiman.

II. ROLL CALL

A quorum was present.

III. PUBLIC COMMENT

None.

IV. APPROVAL OF MINUTES

Motion by Boardmember Reil and second by Boardmember Bergeron to approve the March 1, 2016 LEOFF 1 Disability Board meeting minutes as presented. Motion carried unanimously (4-0).

V. CONSIDERATION OF APPLICATIONS FOR DISABILITY ALLOWANCES

A. Applications for Disability Allowances

Motion by Boardmember Bergeron and second by Councilmember Robinson to approve the Disability Allowances as presented. Motion carried unanimously (4-0).

B. Applications for Disability Allowances Greater than 1 month

None.

VI. CONSIDERATION OF MEDICAL CLAIMS

A. Routine Claims

Motion by Boardmember Bergeron and second by Boardmember Reil to approve the Routine Claims as presented. Motion carried unanimously (4-0).

B. Special Claims

Motion by Councilmember Robinson and second by Boardmember Bergeron to approve the Special Claims as presented.

Councilmember Robinson questioned if Member #58 has researched options for in-network physicians. Ms. Dillon clarified that the Member has explained that there are not any in-network physicians that have an office near the Member that meets the Member's needs.

At the question, motion carried unanimously (4-0).

C. Pre-Approved Recurring Long-Term Care Claims

The pre-approved recurring long-term care claims were reviewed and included in the Board packet.

VII. STAFF REPORT

None.

VIII. UNFINISHED BUSINESS

None.

IX. NEW BUSINESS

None.

X. ANNOUNCE DATE & TIME OF NEXT MEETING

The next Disability Board meeting will be held on May 3, 2016.

XI. ADJOURNMENT

By general consensus, the meeting was adjourned at 6:19 p.m.

CITY OF BELLEVUE
LEOFF 1 DISABILITY BOARD
Meeting Minutes

May 3, 2016
5:30 p.m. – Administration
6:00 p.m. – Business Meeting

Conference Room 1E-118
Bellevue City Hall

MEMBERS PRESENT:	Chairperson Susan Neiman Councilmember Lynne Robinson Councilmember Vandana Slatter
MEMBERS ABSENT:	Boardmember Wayne Bergeron Boardmember Bryan Reil
OTHERS PRESENT:	Paula Dillon, Human Resources Siona Windsor, City Attorney's Office
MINUTES TAKER:	Michelle Cash

I. CALL TO ORDER

The meeting was called to order at 6:09 p.m. by Chair Neiman.

II. ROLL CALL

A quorum was present.

III. PUBLIC COMMENT

None.

IV. APPROVAL OF MINUTES

Approval of the April 5, 2016 meeting minutes was postponed due to a lack of quorum.

V. CONSIDERATION OF APPLICATIONS FOR DISABILITY ALLOWANCES

A. Applications for Disability Allowances

Motion by Councilmember Slatter and second by Councilmember Robinson to approve the Disability Allowances as presented. Motion carried unanimously (3-0).

B. Applications for Disability Allowances Greater than 1 month

None.

VI. CONSIDERATION OF MEDICAL CLAIMS

A. Routine Claims

Motion by Councilmember Robinson and second by Councilmember Slatter to approve the Routine Claims as presented. Motion carried unanimously (3-0).

B. Special Claims

Motion by Councilmember Robinson and second by Councilmember Slatter to approve the Special Claims as presented.

Councilmember Robinson called attention to Member #58's claim. The Member's physician prescribed a medication called "Deplin" for the Member. Express Scripts denied covering the medication, since it is considered a food product. Councilmember Robinson recommended that the claim be denied and that the Member submit the claim to Premera.

Ms. Windsor reviewed the Disability Board Policies & Procedures, specifically Item IV.1.b and Item IV.7 noting that the Board needs to determine if the claim is medically necessary. If the claim is denied by Premera, then the Member may submit the claim to the Board for consideration.

Although Member #58 received a verbal denial of the claim from the pharmacist, the claim was not submitted/processed through the insurance company.

Boardmembers discussed Member #21's claim. Ms. Dillon noted that the Member was recently hospitalized for pneumonia and needed a feeding tube. The Member's needs were reassessed on 04/01/16 and it was determined that the Member needs more care. The Member's care points increased from 34 points ($340 per month) to 276 points ($2,760 per month). The Member's updated care assessment was included in the Board packet. Ms. Dillon noted that the new monthly rate for Member #21 would be $6,160. However, the Board maximum for assisted living in 2016 is $6,000 per month. Ms. Dillon clarified that the Member will pay the remaining balance.

Boardmembers discussed Member #65's claim. Ms. Dillon noted that the Member is taking a compound medication. One of the ingredients is no longer covered under Premera's compound formulary. The claim is the charge for that part of the medication. Boardmembers asked the following questions:

- What has changed in the compounding?
- Did the Member visit a different pharmacy?
- Is the drug no longer covered or did the compound change?

At the question, motion carried unanimously (3-0) to approve the claims for Members #123 and #21; and to deny the claims for Members #58 and #65 pending further information. Boardmembers requested an Explanation of Benefits statement from Member #58. If the Member's claim is denied, then the Member needs to submit an explanation of medical necessity from the Member's physician and explain why the prescription is a medicine or drug, as provided by the statute. Boardmembers requested additional information from Member #65 regarding the compound formula and why the claim was denied.

C. Pre-Approved Recurring Long-Term Care Claims

The pre-approved recurring long-term care claims were reviewed and included in the Board packet.

Boardmembers requested that staff follow-up with Member #9's family to request additional information regarding the Public Comment request that was made at the February 2, 2016 LEOFF 1 Disability Board meeting. Ms. Dillon clarified that Member #9's claim is currently within the allowable amount.

VII. STAFF REPORT

None.

VIII. UNFINISHED BUSINESS

A. Amendment to Board Policy Manual

Ms. Dillon reminded Boardmembers that a motion was approved at the March 1, 2016 Board meeting to direct staff to send to LEOFF 1 Members a copy of the draft amendment adding a new Paragraph 11 and 12 to Section V of the 2014 Restated Disability Board Policy and Procedure Manual. This amendment added verbiage related to reconsideration and appeal process for Board decisions on claims that are denied as not duty related. As part of the process, this information was sent to Members for questions/comments. Ms. Dillon noted that the only comment that was received stated "looks good to me!"

Motion by Councilmember Robinson and second by Councilmember Slatter to amend the 2014 Restated Disability Board Policy and Procedure Manual to add two new paragraphs to Section V. A new Paragraph 11 provides a process for requesting the Board reconsider its denial that disability leave is duty related. A new Paragraph 12 adds that a Member has 30 days to appeal to the King County Superior Court (and 30 days to serve the appeal) from the Board's written notice of denial that disability leave is duty related. Motion carried unanimously (3-0).

IX. NEW BUSINESS

None.

X. ANNOUNCE DATE & TIME OF NEXT MEETING

The next Disability Board meeting will be held on June 7, 2016.

XI. ADJOURNMENT

By general consensus, the meeting was adjourned at 6:37 p.m.

Item No.: VII. B. 1.
June 7, 2016

DISABILITY BOARD AGENDA MEMORANDUM

SUBJECT
The below and attached information is being provided to the Board to assist it in determining whether to pre approve a medical food for reimbursement under the applicable LEOFF 1 statutes.

STAFF CONTACT
Paula Dillon 452-7198

POLICY CONSIDERATION

Should the Disability Board preapprove reimbursement for a requested medical food for the treatment of the identified medical condition as requested by a LEOFF 1 member?

BACKGROUND

RCW 41.26.110 describes the powers of the Disability Board stating:

> "(3) The disability boards authorized for establishment by this section shall perform all functions, exercise all powers, and make all such determinations as specified in this chapter.

RCW 41.26.150 explains that LEOFF 1 members are entitled to have the City pay for their "necessary medical services" as determined by the Board. RCW 41.26.030(19) lists minimum medical services and provides that LEOFF 1 members are entitled to reimbursement for the reasonable charges for these services. Beyond these minimum necessary services, RCW 41.26.150 provides that the Disability Board shall designate the medical services available. Thus the Board has the discretion to designate additional reimbursable necessary medical services available to LEOFF 1 members above the minimums in RCW 41.26.030.

RCW 41.26.030(19) identifies the minimum medical services and includes:
(b) Other medical expenses: The following charges are considered "other medical expenses", provided that they have not been considered as "hospital expenses".
(iii) The charges for the following medical services and supplies:
(A) Drugs and medicines upon a physician's prescription;

The Board has received a request to preapprove reimbursing a member for a medical food. The manufacturers of the product identify it as a "medical food". Attached to this memo is the Food and Drug Administration Guidance for Industry: Frequently Asked Questions About Medical Foods (2016). It states:

> A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."
> FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food (21 CFR 101.9(j)(8)). Medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and

intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition. Not all foods fed to patients with a disease, including diseases that require dietary management, are medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who requires use of the product as a major component of a disease or condition's specific dietary management.

The Guidance also explains that the FDA does not regulate medical foods since they are not drugs; that medical foods must comply with all applicable FDA requirements for foods; and that the FDA does not require that medical foods be made available by written or oral prescription since it is not a prescription drug product.

The City's Premera Plan addresses the coverage of medical foods. It provides in relevant part:

> Benefits for medical foods, as defined below, are subject to your calendar year deductible and coinsurance (if applicable).
>
> This plan covers medically necessary medical foods used to supplement or replace a member's diet in order to treat inborn errors of metabolism. An example is phenylketonuria **(PKU).** In some cases of severe malabsorption (eosinophilic gastrointestinal disease), a medical food called "elemental formula" may be covered.
>
> Medical foods are formulated to be consumed or administered enterally under strict medical supervision. These foods generally provide most of a person's nutrition. Medical foods are designed to treat a specific problem that can be diagnosed by medical tests.
> This benefit does not cover other oral nutrition or supplements not used to treat inborn errors of metabolism, even if a physician prescribes them. This includes specialized infant formulas and lactose-free foods

The 2016 FDA FAQ that is attached also provides additional information on the role of medical foods in treating inborn errors of metabolism (See FAQ. 20 and 21)

OPTIONS

1. Ask the member to submit his physician's most recent (undated) explanation letter (received on May 19, 2016 by staff) to Premera for a medical review (or other appropriate submission, appeal or review) to obtain an answer to whether the medical food requested is covered.
2. Approve the member's May 23, 2016 request for approval of one month of the medical food requested on condition that the purchase information and his doctor's most recent (undated) explanation letter (received on May 19, 2016 by staff) are then submitted to Premera for a determination as identified in Option 1.
3. Approve the March 23, 2016 request for preauthorization of reimbursement of the medical food after considering the above and attached information and the information submitted by the member.
4. Deny the March 23, 2016 request after considering the above and attached information and the information submitted by the member.
5. Submit questions to the member's doctor to obtain more information to assist the Board in making a determination on whether this medical food should be considered a necessary medical service.

ATTACHMENTS

1. Food and Drug Administration .Guidance for Industry: Frequently Asked Questions About Medical Foods (2016)
2. City of Bellevue LEOFF Employees & Dependents Your Choice. 101643 (2015), page 14 (Medical Food), page 28 (Exclusions), and page 34 (Drugs and Food Supplements)
3. Premera Medical Policy – Home Enteral Nutrition (2016)
4. Premera Appeal Rights

ATTACHMENT

1

Contains Nonbinding Recommendations

Frequently Asked Questions About Medical Foods; Second Edition

Guidance for Industry

Additional copies are available from:
Office of Nutrition and Food Labeling, HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 240-402-2373
http://www.fda.gov/FoodGuidances

You may submit written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
May 2016

Table of Contents

Frequently Asked Questions About Medical Foods

Guidance for Industry[1]

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance is intended to provide industry with a convenient place to find answers to frequently asked questions (FAQs) about medical foods. The responses to these FAQs address common questions about the definition of and regulations for medical foods. This guidance is a second edition of the May 2007 guidance titled "Guidance for Industry: Frequently Asked Questions About Medical Foods." This guidance provides responses to additional questions regarding the definition and labeling of medical foods and updates some of the prior responses.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidances means that something is suggested or recommended, but not required.

II. Questions and Answers

1. **What is a medical food?**

   A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary

[1] This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food (21 CFR 101.9(j)(8)). Medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition. Not all foods fed to patients with a disease, including diseases that require dietary management, are medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who requires use of the product as a major component of a disease or condition's specific dietary management.

2. **Has FDA established by regulation any criteria that clarify the statutory definition of a medical food?**

   Yes. The following criteria that clarify the statutory definition of a medical food can be found in FDA's regulations at 21 CFR 101.9(j)(8). A medical food is exempt from the nutrition labeling requirements of 21 CFR 101.9 only if:

   a. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube, meaning a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine;[2]
   b. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

[2] Enteral feeding can be achieved by oral intake or by tube. Enteral feeding by tube refers to a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine. These enteral feedings should not be confused with parenteral (or intravenous) nutrient formulations.

c. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
d. It is intended to be used under medical supervision; and
e. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

We discuss nutrition labeling requirements and medical foods in questions 4 to 6 below.

3. **Does FDA regulate medical foods as drugs?**

No. Medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs.

4. **Do the labeling requirements for nutrient content claims apply to medical foods?**

Medical foods are exempt from the labeling requirements for nutrient content claims under the Nutrition Labeling and Education Act of 1990 (see 21 U.S.C. 343(r)(5)(A)). As with any food, a medical food that bears a false or misleading claim would be considered misbranded under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

5. **Do the labeling requirements for health claims apply to medical foods?**

Medical foods are exempt from the labeling requirements for health claims under the Nutrition Labeling and Education Act of 1990 (see 21 U.S.C. 343(r)(5)(A)). As with any food, a medical food that bears a false or misleading claim would be considered misbranded under section 403(a)(1) of the FD&C Act.

6. **What labeling requirements apply to medical foods?**

The labeling for medical foods must comply with all applicable food labeling requirements except for those specific requirements from which medical foods are exempt.

Specifically, the labeling of medical foods must contain:

- A statement of identity (21 CFR 101.3);
- An accurate statement of the net quantity of contents (21 CFR 101.105);
- The name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5); and

- A complete list of ingredients, listed by their common or usual name and in descending order of predominance (21 CFR 101.4).

In addition, all words, statements, and other information required by or under authority of the FD&C Act to appear on a label or labeling of a medical food must appear with prominence and conspicuousness (21 CFR 101.15) and be in English except that, for medical foods distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English (21 CFR 101.15(c)(1)). Further, if a label bears any representation in a foreign language, then all mandatory label information must be repeated in each foreign language used on the label (21 CFR 101.15(c)(2)).

Medical food labels must also conform with the principal display panel requirements under 21 CFR 101.1 and the applicable information panel requirements under 21 CFR 101.2. Further, the requirements concerning the misbranding of food (21 CFR 101.18) apply to medical foods.

7. What other FDA requirements apply to medical foods?

Manufacturers of medical foods must comply with all applicable FDA requirements for foods, including the following regulations:

- Current good manufacturing practice (21 CFR part 110);
- Registration of food facilities (21 CFR part 1 subpart H);
- Thermally processed low-acid foods packaged in hermetically sealed containers (21 CFR part 113);
- Acidified foods (21 CFR part 114); and
- Emergency permit control (21 CFR part 108).

8. Does the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) apply to medical foods?

Yes. FALCPA's labeling requirements apply to all foods other than raw agricultural commodities, including medical foods.

9. Where can I find more information on FALCPA's labeling requirements?

You can find more information on FALCPA's labeling requirements on FDA's Web site.

10. **What are the registration requirements for medical food facilities?**

Any facility engaged in manufacturing, processing, packing, or holding medical foods for consumption in the United States must register with FDA.[3] You can find additional information regarding the registration of food facilities on FDA's Web site.

11. **Does FDA maintain a list of medical foods?**

FDA does not maintain a comprehensive list of medical food products.

12. **Is there a compliance program guidance manual for medical foods?**

Yes. FDA has a compliance program guidance manual entitled "Medical Foods Program - Import and Domestic" that is available on FDA's Web site.

13. **What is the purpose of FDA's compliance program for medical foods?**

FDA's compliance program gives direction to FDA inspectors on: (1) obtaining information regarding the manufacturing/control processes and quality assurance programs employed by domestic manufacturers of medical foods through establishment inspections; (2) collecting domestic and import surveillance samples of medical foods for nutrient and microbiological analyses; and (3) recommending action when significant violations of the FD&C Act (or related regulations) are found.

14. **Does FDA require that medical foods be made available by written or oral prescription?**

No. The requirement for a written or oral prescription in section 503(b) of the FD&C Act and its implementing regulations at 21 CFR 201.100 only applies to the dispensing of prescription drug products. The Orphan Drug Act provides that medical foods must be formulated to be consumed or administered enterally under the supervision of a physician, but there is no requirement for a prescription.

15. **How does FDA interpret "under the supervision of a physician"?**

FDA considers the requirement that a medical food be formulated to be consumed or administered enterally under the supervision of a physician to mean that the intended use of a medical food is for the dietary management of a patient receiving active and ongoing medical supervision (e.g., in a health care facility or as an outpatient) by a physician who has determined that the medical food is necessary to the patient's overall medical care. The patient should generally see the physician on a recurring

[3] See section 415 of the FD&C Act (21 U.S.C. 350d).

basis for, among other things, instructions on the use of the medical food as part of the dietary management of a given disease or condition.

16. **May the labeling of a medical food bear the symbol "Rx only"?**

The labeling of medical foods may **not** bear the symbol "Rx only." Section 503(b)(4)(A) of the FD&C Act (21 U.S.C. 353(b)(4)(A)) provides that a prescription drug is misbranded if the label of the drug fails to bear, at a minimum, the symbol "Rx only" to indicate that the product may not lawfully be dispensed without a prescription. Unlike prescription drugs, medical foods are not required by federal law to be dispensed by prescription. Therefore, the use of the symbol "Rx only" in the labeling of a medical food would misbrand a medical food under section 403(a)(1) of the FD&C Act because it would be a false and misleading statement about that product. However, because medical foods are required by statute to be formulated to be consumed or administered enterally *under the supervision of a physician*, FDA would not object to the use of language to communicate this requirement in the labeling of a medical food product that is not false or misleading (e.g., "must be used under the supervision of a physician").

17. **Should National Drug Code (NDC) numbers be used in the labeling of medical foods?**

The labeling of medical foods should **not** include NDC numbers. Drug products are identified and reported using a unique, three-segment number, called the NDC, which is a universal product identifier for human drugs.[4] NDC numbers are intended for uniquely identifying drugs and should not be used in the labeling of medical foods since they are not drugs. The presence of an NDC number on a food product that is not a drug misbrands the product under section 403(a)(1) of the FD&C Act. In addition, any representation that creates an impression of official FDA approval through the use of an NDC number in labeling constitutes misbranding.[5]

18. **What requirements apply to ingredients added to medical foods?**

An ingredient that is added to a medical food should be safe and in compliance with all applicable provisions of the FD&C Act and FDA regulations. Any ingredient added to a medical food should be: (1) a food additive used in accordance with FDA's food additive regulations (see 21 CFR part 172); (2) a color additive used in accordance with the color additive regulations (see 21 CFR parts 73 and 74); (3) a substance that is generally recognized, by qualified experts, to be safe under the

[4] See section 510(e) of the FD&C Act (21 U.S.C. 360(e)); 21 CFR 207.35.

[5] See 21 CFR 207.39.

conditions of its intended use (generally recognized as safe (GRAS)) (see 21 CFR 170.30 and 21 U.S.C. 321(s)); or (4) a substance that is authorized by a prior sanction (see 21 CFR 170.3(l), 21 U.S.C. 321(s)(4)).

19. **Where can I find additional information on food additives and GRAS ingredients?**

    Additional information on food additives and GRAS ingredients can be found under the food topic "Ingredients, Packaging & Labeling" on FDA's Web site.

20. **Does FDA generally consider inborn errors of metabolism (IEMs) to be diseases or conditions that a medical food could be used to manage?**

    Yes. FDA generally considers IEMs to be diseases or conditions that a medical food could be used to manage. IEMs include inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate. As a result of diminished or absent enzyme activity in these disorders, certain compounds accumulate in the body to toxic levels, and levels of other compounds that the body normally makes may become deficient (Ref. 1). Without appropriate and accessible management, these metabolic disturbances can lead to a host of medical and developmental consequences ranging from intellectual disability to severe cognitive impairment and even death (Ref. 1). Management may include one or a combination of the following: drug therapy, modification of the normal diet, or use of a medical food.[6]

    Some of these disorders can be managed with modification of the normal diet alone (e.g., reduction of galactose and lactose for galactosemia). However, others cannot be managed solely with diet modification. For these IEMs, a medical food is required in addition to a specific dietary modification in order to obtain adequate levels of essential nutrients (e.g., essential amino acids, essential fatty acids) that are restricted by modifying the normal diet. Medical foods become indispensable for individuals with these IEMs in order to meet the daily requirements of essential nutrients and to limit the metabolic disturbances associated with the particular IEM (e.g., see question 21).

21. **Are there any examples of specific IEMs that medical foods could be used to manage?**

[6] Medical foods may also include infant formulas used for IEM which are regulated as exempt infant formulas under section 412(h)(1) of the FD&C Act; 21 CFR 107.50.

Yes. Some examples of specific IEMs that medical foods could be used to manage involve amino acid/protein, organic acid, or fatty acid metabolism. These IEMs primarily require significant restriction of particular amino acids and/or total protein such as in phenylketonuria (phenylalanine restriction), ornithine transcarbamylase deficiency (nonessential amino acid restriction), methylmalonic acidemia (isoleucine, methionine, threonine, and valine restriction), or significant modification of fatty acids/total fat such as in very long-chain acyl-CoA dehydrogenase deficiency (long chain fatty acid restriction with an increase in medium chain fatty acid levels).

22. **Does FDA consider pregnancy to be a disease?**

FDA does not consider pregnancy to be a disease.[7]

23. **Are there distinctive nutritional requirements associated with pregnancy?**

No. There are no distinctive nutritional requirements associated with pregnancy. Essential nutrient requirements to support pregnancy can be met by diet modification. The Institute of Medicine (IOM) established nutrient recommendations to meet essential nutrient requirements associated with pregnancy. Pregnancy is one of the twelve life stage groups identified by the IOM. For each life stage group, where data were available, IOM established dietary reference intakes (DRIs) to apply to the healthy general population. DRIs are standards for apparently healthy people and are not meant to be applied to those with acute or chronic disease or for the repletion of nutrient levels in previously deficient individuals (Ref. 2).

24. **Does FDA consider pregnancy to be a condition for which a medical food could be labeled and marketed?**

Under 21 CFR 101.9(j)(8)(ii), a medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone. While some diets *may* not supply the full amount of nutrients necessary for women who are pregnant or planning to become pregnant, generally the levels of micronutrients necessary for pregnancy *can* be achieved by the modification of the normal diet alone. It is generally practicable for women who are pregnant or planning to become pregnant to follow the IOM and FDA recommendations for nutrient intake within a normal diet. Therefore, FDA generally would not consider a product labeled and marketed for pregnancy to meet the regulatory criteria for a medical food.

[7] See, e.g., 65 FR 999 at 1000 (Jan. 6, 2000); 63 FR 23623 at 23627 (Apr. 29, 1998).

25. **Are there distinctive nutritional requirements associated with the management of diabetes mellitus (DM)?**

    No. There are no distinctive nutritional requirements associated with the management of DM. Essential nutrient requirements for individuals affected by DM are no different than those for unaffected (generally healthy) persons. Following an individualized healthy, well-balanced diet is crucial to managing conditions such as DM. There are nutritional recommendations established for persons to manage DM (Refs. 3, 4, and 5).

26. **Does FDA consider DM to be a condition for which a medical food could be labeled and marketed?**

    No. Diet therapy is the mainstay of diabetes management. A regular diet can be modified to meet the needs of an individual affected by DM (along with appropriate drug therapy if necessary). Under 21 CFR 101.9(j)(8)(ii), a medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.

27. **Does FDA consider diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) to be diseases for which a medical food could be labeled and marketed?**

    No. Diseases (e.g., scurvy, pellagra) that result from essential nutrient deficiencies (e.g., deficiencies of vitamin C, niacin) are primarily caused by inadequate intake (e.g., famine, significant calorie restriction, eating disorders, alcoholism, diet practices/fad diets). The deficiencies, excluding any permanent physical damage, can typically be corrected once foods with these essential nutrients (or dietary supplements, if necessary) are made available and/or consumed. Because such diseases can typically be managed through consumption of a healthy, well-balanced diet, FDA generally would not consider a product labeled and marketed for these diseases to meet the statutory and regulatory criteria for a medical food (see 21 CFR 101.9(j)(8)(ii)).

28. **Does FDA consider conventional foods that, in their natural state, do not contain protein or are low in protein to meet the definition of a medical food?**

    No. Conventional foods such as fruits, certain vegetables, fats, and sugars generally are not specially formulated to be significantly low in protein or to contain no protein—instead, they are low in protein in their natural state. Under 21 CFR 101.9(j)(8)(i), a medical food must be a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial

or exclusive feeding of a patient by means of oral intake or enteral feeding by tube. Therefore, conventional foods that do not ordinarily contain protein or are ordinarily low in protein would not meet the statutory and regulatory criteria for medical foods.

III. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of April 12, 2016, FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after April 12, 2016.

1. Camp, K., Lloyd-Puryear, M., Huntington, K. Nutritional treatment for inborn errors of metabolism: Indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. Molecular Genetics and Metabolism, 107:3-9, 2012. Available: http://www.ncbi.nlm.nih.gov/pubmed/22854513.

2. Otten, J., Hellwig, J., Meyers, L. eds. Institute of Medicine. Dietary Reference Intakes. The Essential Guide to Nutrient Requirements, Part 1: Development and Application, Introduction to the Dietary Reference Intakes and Applying the Dietary Reference Intakes, pp. 5-17, 2006.

3. American Diabetes Association. Nutrition Therapy Recommendations for the Management of Adults With Diabetes. A Position Statement of the American Diabetes Association. Diabetes Care, 37(1):S120-S143, January 2014. Available: http://care.diabetesjournals.org/content/37/Supplement_1/S120.full.pdf+html.

4. Standards of Medical Care in Diabetes 2016, American Diabetes Association, Diabetes Care. 39 (Supplement 1): S1-S112, January 2016. Available: http://professional.diabetes.org/content/clinical-practice-recommendations.

5. Centers for Disease Control and Prevention. Eat Right! www.cdc.gov/diabetes/consumer/eatright.htm (accessed April 12, 2016).

ATTACHMENT

2

City of Bellevue

LEOFF Employees and Dependents

Your Choice™

1016431

PREMERA | BLUE CROSS

INTRODUCTION

This plan is self-funded by City of Bellevue, which means that City of Bellevue is financially responsible for the payment of plan benefits. City of Bellevue ("the Group") has the final discretionary authority to determine eligibility for benefits and construe the terms of the plan.

City of Bellevue has contracted with Premera Blue Cross, an Independent Licensee of the Blue Cross Blue Shield Association, to perform administrative duties under the plan, including the processing of claims. City of Bellevue has delegated to us the discretionary authority to determine eligibility for benefits and to construe the terms used in this plan to the extent stated in our administrative services contract with the Group. Premera Blue Cross doesn't insure this plan. In this booklet Premera Blue Cross is called the "Claims Administrator." This booklet replaces any other benefit booklet you may have.

This plan will comply with the 2010 federal health care reform law, called the Affordable Care Act (see "Definitions"). If Congress, federal or state regulators, or the courts make further changes or clarifications regarding the Affordable Care Act and its implementing regulations, this plan will comply with them even if they are not stated in this booklet or if they conflict with statements made in this booklet.

Group Name:	City of Bellevue
Effective Date:	January 1, 2015
Group Number:	1016431
Plan:	Your Choice (Non-Grandfathered) Plan C
Certificate Form Number:	COB2015B

HOW TO USE THIS BOOKLET

This booklet will help you get the most out of your benefits. Every section contains important information, but the ones below may be particularly useful:

- **How Does Selecting A Provider Affect My Benefits?** — how using network providers will cut your costs
- **What Types Of Expenses Am I Responsible For Paying?**
- **What Are My Benefits?** — what's covered and what you need to pay for covered services.
- **Prior Authorization** — Describes the plan's prior authorization and emergency admission notification requirements.
- **What's Not Covered?** — services that are either limited or not covered under this plan
- **Who Is Eligible For Coverage?** – eligibility requirements for this plan
- **How Do I File A Claim?** — step-by-step instructions for claims submissions
- **Complaints And Appeals** — processes to follow if you want to file a complaint or an appeal
- **Definitions** — terms that have specific meanings under this plan. Example: "You" and "your" refer to members under this plan. "We," "us" and "our" refer to Premera Blue Cross.

FOR MORE INFORMATION

You'll find our contact information on the back cover of this booklet. Please call or write Customer Service for help with:

- Questions about benefits or claims
- Questions or complaints about care you receive
- Changes of address or other personal information

You can also get benefit, eligibility and claim information through our Interactive Voice Response system when you call.

Online information about your plan is at your fingertips whenever you need it

You can use our Web site to:

- Locate a health care provider near you
- Get details about the types of expenses you're responsible for and this plan's benefit maximums
- Check the status of your claims
- Visit our health information resource to learn about diseases, medications, and more

TABLE OF CONTENTS

Medical Supplies, Orthotics (Other Than Foot Orthotics), and Orthopedic Appliances

Benefits for these services are paid by the plan as follows when you use a network provider:

LEOFF Employees..... 100%

Dependent - Affordable.....90% subject to deductible

Dependent – Core..... 100%

Covered services include, but aren't limited to, dressings, braces, splints, rib belts and crutches, as well as related fitting expenses.

For hypodermic needles, lancets, test strips, testing agents and alcohol swabs benefit information, please see the Prescription Drugs benefit.

Please Note: This benefit does not include medical equipment or supplies provided as part of home health care. See the Home and Hospice Care benefit for coverage information.

Prosthetics

Benefits for external prosthetic devices (including fitting expenses) as stated below, are provided when such devices are used to replace all or part of an absent body limb or to replace all or part of the function of a permanently inoperative or malfunctioning body organ. Benefits will only be provided for the initial purchase of a prosthetic device, unless the existing device can't be repaired, or replacement is prescribed by a physician because of a change in your physical condition.

Please Note: This benefit does not include prosthetics prescribed or purchased as part of a mastectomy or breast reconstruction. Please see the Mastectomy and Breast Reconstruction Services benefit for coverage information.

Benefits for prosthetics are not subject to a benefit maximum.

Foot Orthotics and Therapeutic Shoes

Benefits are provided for foot orthotics (shoe inserts) and therapeutic shoes (orthopedic), including fitting expenses.

Benefits for these services are paid by the plan as follows when you use a network provider:

LEOFF 1 Employee 100%

LEOFF 2 Employee ..... 100% up to $300 per calendar year

Dependent - Affordable..... Not Covered

Dependent – Core..... 100% up to $300 per calendar year

Breast Pumps

This benefit covers the purchase of a standard electric breast pumps. Rental of hospital grade breast pumps is also covered when medically necessary. Purchase of hospital-grade pumps is not covered.

For further information, please see the Preventive Care benefit.

This benefit doesn't cover:

- Supplies or equipment not primarily intended for medical use
- Special or extra-cost convenience features
- Items such as exercise equipment and weights
- Whirlpools, whirlpool baths, portable whirlpool pumps, sauna baths, and massage devices
- Over bed tables, elevators, vision aids, and telephone alert systems
- Structural modifications to your home or personal vehicle
- Orthopedic appliances prescribed primarily for use during participation in sports, recreation or similar activities
- Penile prostheses
- Prosthetics, intraocular lenses, appliances or devices requiring surgical implantation. These items are covered under the Surgical Services benefit. Items provided and billed by a hospital are covered under the Hospital Inpatient Care or Hospital Outpatient Care benefits.

Medical Foods

Benefits for medical foods, as defined below, are subject to your calendar year deductible and coinsurance (if applicable).

This plan covers medically necessary medical foods used to supplement or replace a member's diet in order to treat inborn errors of metabolism. An example is phenylketonuria (PKU). In some cases of severe malabsorption (eosinophilic gastrointestinal disease), a medical food called "elemental formula" may be covered.

Medical foods are formulated to be consumed or administered enterally under strict medical supervision. These foods generally provide most of a person's nutrition. Medical foods are designed to treat a specific problem that can be diagnosed by medical tests.

This benefit does not cover other oral nutrition or supplements not used to treat inborn errors of metabolism, even if a physician prescribes them. This includes specialized infant formulas and lactose-free foods.

Mental Health Care

Benefits for mental health services, including treatment of eating disorders (such as anorexia nervosa, bulimia or any similar condition), are provided as stated below.

For benefit information concerning therapeutic devices, appliances, medical equipment, medical supplies, diabetic equipment and accessories (except for those specifically stated as covered in this benefit), please see the Medical Equipment and Supplies benefit.

Benefits for immunization agents and vaccines, including the professional services to administer the medication, are provided under the Preventive Care benefit.

Exclusions

This benefit doesn't cover:

- Drugs and medicines that may be lawfully obtained over the counter (OTC) without a prescription. OTC drugs are excluded even if prescribed by a practitioner, unless otherwise stated in this benefit. Examples of such non-covered items include, but aren't limited to non-prescription drugs and vitamins, food and dietary supplements, herbal or naturopathic medicines and nutritional and dietary supplements (e.g. infant formulas or protein supplements).
- Non-participating mail-order pharmacies
- Non-prescription male contraceptive methods, such as condoms, even if prescribed
- Non-prescription contraceptive methods (e.g. jellies, creams, foams or devices)
- Drugs for the purpose of cosmetic use, or to promote or stimulate hair growth (e.g. wrinkles or hair loss)
- Drugs for experimental or investigational use
- Biologicals, blood or blood derivatives
- Any prescription refilled in excess of the number of refills specified by the prescribing provider, or any refill dispensed after one year from the prescribing provider's original order
- Drugs dispensed for use or administration in a health care facility or provider's office, or take-home drugs dispensed and billed by a medical facility. The exceptions are for prescription drugs provided as part of the plan's Specialty Pharmacy provision (see "Specialty Pharmacy Program" earlier in this benefit), which are payable under this benefit, regardless of where they are administered.
- Replacement of lost or stolen medication
- Infusion therapy drugs or solutions and drugs requiring parenteral administration or use, and injectable medications. (The exception is self-administered injectable diabetic drugs.) Please see the Infusion Therapy benefit.
- Weight management drugs
- Therapeutic devices, appliances, medical equipment, medical supplies, diabetic equipment and accessories (except for those specifically stated as covered in this benefit). Please see the Medical Equipment and Supplies benefit for available coverage.
- Immunization agents and vaccines, except as stated in the Preventive Care benefit.
- Drugs to treat infertility, including fertility enhancement medications

Questions and Answers About Your Pharmacy Benefits

1. **Does this plan exclude certain drugs my health care provider may prescribe, or encourage substitution for some drugs?**

   The plan's prescription drug benefit makes use of our pharmacy drug list. (This is sometimes referred to as a "formulary.") We review medical studies, scientific literature and other pharmaceutical information to choose safe and effective drugs for the list.

   This plan encourages the use of appropriate "generic drugs" (as defined below). When available and indicated by the prescriber, a generic drug will be dispensed in place of a brand name drug.

   A "generic drug" is a prescription drug product manufactured and distributed after the brand name drug patent of the innovator company has expired. Generic drugs have obtained an AB rating from the U.S. Food and Drug Administration and are considered by the FDA to be therapeutically equivalent to the brand name product. For the purposes of this plan, classification of a particular drug as a generic is based on generic product availability and cost as compared to the reference brand name drug.

   It's important to note that this plan provides benefits for non-preferred brand name drugs, but at a higher cost to you.

   In no case will your out-of-pocket expense exceed the cost of the drug or supply.

   This plan doesn't cover certain categories of drugs. These are listed above under "Exclusions."

   Certain drugs are subject to prior authorization. As part of this review, some prescriptions may require additional medical information from the prescribing provider, or substitution of equivalent medication. Please see "Prior Authorization" in the Care Management section of your booklet for additional detail.

2. **When can my plan change the pharmacy drug list? If a change occurs, will I have to pay more to use a drug I had been using?**

   Our Pharmacy and Therapeutics Committee reviews the pharmacy drug list frequently throughout the year. This committee includes

Drugs And Food Supplements

Over-the-counter drugs, solutions, supplies, food and nutritional supplements other than those covered under the Medical Foods benefit; over-the-counter contraceptive drugs (except as required by law), supplies and devices; herbal, naturopathic, or homeopathic medicines or devices; hair analysis; and vitamins that don't require a prescription, except as required by law.

Environmental Therapy

Therapy designed to provide a changed or controlled environment.

Experimental Or Investigational Services

Any service or supply that Premera Blue Cross determines is experimental or investigational on the date it's furnished, and any direct or indirect complications and aftereffects thereof. Our determination is based on the criteria stated in the definition of "experimental/investigational services" (please see the "Definitions" section in this booklet).

If we determine that a service is experimental or investigational, and therefore not covered, you may appeal our decision. Please see the "Complaints And Appeals " section in this booklet for an explanation of the appeals process.

Family Members Or Volunteers

- Services or supplies that you furnish to yourself or that are furnished to you by a provider who is an immediate relative. Immediate relative is defined as spouse, natural or adoptive parent, child, sibling, stepparent, stepchild, stepsibling, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-in-law, grandparent, grandchild, spouse of grandparent or spouse of grandchild
- Services or supplies provided by volunteers, except as specified in the Home and Hospice Care benefit

Gender Transformations

Treatment or surgery to change gender, including any direct or indirect complications and after effects thereof.

Governmental Medical Facilities

Services and supplies furnished by a governmental medical facility, except when:

- Your request for a benefit level exception for non-emergent care to the facility is approved. (Please see "Services From Non-Network Providers" in the "Prior Authorization" subsection in this booklet)
- You're receiving care for a "medical emergency" (please see the "Definitions" section in this booklet)
- The plan must provide available benefits for covered services as required by law or regulation

Hair Loss

- Drugs, supplies, equipment, or procedures to replace hair, slow hair loss, or stimulate hair growth
- Hair prostheses, such as wigs or hair weaves, transplants, and implants

Hearing Hardware

- Hearing aids and devices used to improve hearing sharpness, except as covered under the LEOFF and Core Medical plans.
- Hearing aids (including batteries and related equipment) that exceed the maximum benefit per member in a period of 3 consecutive calendar years. These expenses are also not eligible for coverage under other benefits of this plan.
- Batteries or other ancillary equipment other than that obtained upon purchase of hearing aids
- Hearing aids that exceed the specifications prescribed for correction of hearing loss
- Expenses incurred after your coverage under this plan ends unless hearing aids were ordered before that date and were delivered within 90 days after the date your coverage ended

Human Growth Hormone Benefit Limitations

Benefits for human growth hormone are only provided under the Specialty Pharmacy Program (please see the Prescription Drugs benefit) and are not covered to treat idiopathic short stature without growth hormone deficiency.

Illegal Acts and Terrorism

This plan does not cover illness or injuries resulting from a member's commission of:

- A felony (does not apply to a victim of domestic violence)
- An act of terrorism
- An act of riot or revolt

Infertility, Assisted Reproduction And Sterilization Reversal

- Treatment and enhancement of infertility, including procedures, supplies and drugs
- Any assisted reproduction techniques, regardless of reason or origin of condition, including but not limited to, artificial insemination, in-vitro fertilization, and gamete intra-fallopian transplant (GIFT) and any direct or indirect complications thereof
- Reversal of surgical sterilization, including any direct or indirect complications thereof

ATTACHMENT

3

PREMERA BLUE CROSS

MEDICAL POLICY

Home Enteral Nutrition

Number 8.01.502
Effective Date February 9, 2016
Revision Date(s) 02/09/16; 11/20/15; 05/27/15; 04/14/15; 02/25/15; 05/02/14; 12/18/13; 05/28/13; 05/22/12; 06/13/11; 05/11/10; 08/11/09; 06/09/09; 07/08/08, 04/10/07; 06/02/06; 04/11/06; 05/10/05; 09/01/04; 05/11/04; 01/01/04; 08/12/03; 04/15/03; 05/14/02; 05/08/01; 03/02/99; 08/04/98
Replaces 1.02.01

Policy

[TOP]

Oral (taken by mouth) Enteral Nutrition

Oral nutrition or supplements may be considered **medically necessary** when used for the treatment of inborn errors of metabolism, such as (not an all-inclusive list, *see Policy Guidelines*):

- Histidinemia
- Homocystinuria
- Maple syrup urine disease (MSUD)
- Phenylketonuria (PKU)
- Tyrosinemia

For Washington Members only: Elemental enteral formula given orally or via feeding tube may be considered **medically necessary** when all of the following criteria are met:

- There is a diagnosis of eosinophilic gastrointestinal associated disorders (eosinophilic esophagitis, eosinophilic gastroenteritis, or eosinophilic colitis), and
- There is a prescription, and
- The provider supervises the use of the elemental formula.

For Oregon Members only: Elemental enteral formula given orally or via feeding tube may be considered **medically necessary** when all of the following criteria are met:

- There is a diagnosis of severe intestinal malabsorption, and
- There is a prescription, and
- The elemental formula comprises the sole source, or an essential source of nutrition.

Enteral Nutrition via Feeding Tube

Enteral nutritional support via feeding tube may be considered **medically necessary** for providing nutrition for patients with:

- Adequate intestinal absorption despite:
    - disorders of the gastrointestinal tract (e.g., head and neck cancer, an obstructing tumor or stricture of the esophagus or stomach, or Crohn's disease);
    - central nervous system disease or injury resulting in interference with neuro-muscular coordination of chewing and swallowing that presents a risk of aspiration;

- Anorexia or bulimia, when the patient meets criteria listed under policy guidelines; or
- Failure to thrive.

Related Policies

[TOP]

N/A

Policy Guidelines

[TOP]

Oral (taken by mouth) Enteral Nutrition

Specially formulated medical nutrition/supplements taken by mouth due to inborn errors of metabolism are eligible for coverage as medical supplies as long as the physician treating the patient indicates the dietary intake is required to prevent physical and/or neurological injury and the dietary requirements cannot be met by management of nutritional intake using over-the-counter food sources.

In addition to those inborn errors of metabolism listed in the policy statement, there may rarely be other inborn errors of metabolism for which supplements are requested. There are hundreds of types of inborn errors of metabolism; therefore, not all could be listed within the policy. Not all inborn errors of metabolism require special foods for treatment. These requests must be reviewed and approved by a medical director on a case-by-case basis.

Brief Description	ICD-9 code	ICD-10 code
histidemia	270.5	E70.41
homocystinuria	270.4	E72.11
maple syrup urine disease (MSUS)	270.3	E71.0
tyrosinemia type 1	270.0	E70.21
phenylketonuria (PKU)	270.1	E70.0

Enteral Nutrition via tube

The following criteria must be met prior to the initial implementation of enteral nutrition services.

- The patient receives no more than 30% of his/her caloric intake orally *OR* is unable to maintain estimated nutritional needs even though he may be receiving >30% orally (e.g., cystic fibrosis or failure to thrive).

For anorexia or bulimia, the patient must meet the following criteria:

- Enteral nutrition (EN) should be temporary until such time as the patient is able to take in and retain adequate amounts orally to correct the specific physical abnormalities and maintain the corrected state. Within one week of beginning EN, attempts at oral feedings should be made. An additional week may be required to wean off EN. Concomitant psychotherapy to address the underlying psychological reasons for pathological restricting of intake and/or purging is mandatory.

Physician supervision: periodic assessment of nutritional status by a provider with prescriptive authority.

Note: A physician must specifically order nutrients and the manner of administration for EN, medical food, and for oral nutrition supplies for the treatment of inborn errors of metabolism. However, a physician order for the nutritional support does not, in itself, qualify the service or supply for coverage.

Description

[TOP]

Enteral nutrition is nutritional support given via the alimentary canal or any route connected to the gastrointestinal system (i.e., the enteral route). This includes oral feeding, sip feeding, and tube feeding using nasogastric, gastrostomy, and jejunostomy tubes. (1)

Background

Most enteral feeds are ready-to-use fluids, in microbial-free containers that provide macronutrients, micronutrients, fluids and, in some cases, soluble or insoluble fiber. They are usually nutritionally complete within a specific volume, providing the necessary nutrients to support the dietary needs of the patient.(2)

Table 1. Classification of enteral feeds. (2)

Type of Feed/formula	Description
Disease-specific enteral formula	**Designed for specific clinical conditions and metabolic disorders (i.e. chronic renal failure, respiratory disease, diabetes, cancer). Expensive**
General feeds (polymeric)	For patients with normal digestion and absorption. They contain whole proteins. Usual osmolarity: 300-500 mOsm/kg, 1-1.2 kcal/ml, 30-40 g protein/l
Hydrolysed/elemental	**For patients with limited GI function. They contain free amino acids, low in fat and low residue. Hyperosmotic, 1 kcal/ml, 40 g protein/L. Expensive**
Semi-elemental/partially hydrolyzed/peptide feeds	For patients with disturbed GI function, who need partially hydrolysed nutrients for better digestion and absorption. Osmolarity: depends on the level of hydrolysis, 1-1.2 kcal/ml, 30-45 g protein/l. Relatively expensive

Elemental and semi-elemental feeds facilitate digestion and absorption in patients with a problematic GI function. They are indicated for patients with inflammatory bowel disease, pancreatic insufficiency, malabsorption, short bowel syndrome, radiation enteritis, early enteral feeding or intolerance to polymeric feeds.(2)

Treatment for most metabolic disorders includes exclusion of specific nutritional elements present in common diets. Special formulas are required for infants and children with these disorders to prevent or restrict physical and/or neurological injury that results from faulty metabolism. Continuation of dietary restrictions may be life-long.

Malabsorption of ingested food has many causes. Shortening of the small bowel (usually via surgical resection) and mucosal damage (celiac disease) both reduce surface area. Impaired motility interferes with normal propulsive movements and mixing of food with pancreatic and biliary secretions. Dysmotility also allows anaerobic bacteria proliferation with subsequent bacterial overgrowth and increased carbohydrate fermentation with resultant acidic diarrhea. Another problem of bacterial overgrowth occurs when bacterial deconjugation of bile acids leads to fat malabsorption as seen in intestinal pseudo-obstruction, postoperative blind loop syndrome. Impaired intestinal lymphatic (congenital lymphangiectasia) or venous drainage also causes malabsorption. Diseases reducing pancreatic exocrine function (cystic fibrosis, Shwachman syndrome) or the production and flow of biliary secretions cause nutrient malabsorption. Malabsorption of specific nutrients may be genetically determined (disaccharidase deficiency, glucose-galactose malabsorption, and abetalipoproteinemia).(3)

Gastrointestinal eosinophilia, a broad term for abnormal eosinophil accumulation in the gastrointestinal tract, involves many different disease identities. (4). Eosinophilic digestive diseases (EDD) are relatively rare disorders associated with increased gastrointestinal eosinophilic infiltrates without any underlying primary etiology. The pathophysiology of EDD is unclear, but is suspected to be related to a hypersensitivity reaction given its correlation with other atopic disorders and clinical response to corticosteroid therapy. Current management is extrapolated from therapies for other atopic conditions. The mainstay of therapy is corticosteroids and avoidance of food antigens.(5)

Regulatory Status

Enteral formulas are considered food supplements by the Food and Drug Administration (FDA) and are therefore not under the same regulatory control as medications. As a result, enteral formula labels may make "structure and function" claims without prior FDA review or approval. Furthermore, there is a lack of prospective,

randomized, controlled clinical trials supporting the purported indications for the majority of the specialized formulas currently on the market.

Medical Food: defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3) as:
A food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Available at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm. Accessed January, 2016.

Scope

[TOP]

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Benefit Application

[TOP]

Regular food products, nutritional supplements or formula are considered **contract exclusions**, including but not limited to:

- Baby food,
- Banked breast milk,
- Food thickeners,
- Food supplements for a deficient diet,
- Food supplements to provide alternative nutrition in the presence of conditions such as hypoglycemia, allergies, obesity and gastrointestinal disorders,
- Gluten-free food products,
- High protein powders and mixes,
- Lactose-free products; products to aid in lactose digestion,
- Low carbohydrate diets,
- Normal grocery items,
- Nutritional supplement puddings,
- Oral vitamins and minerals,
- Standardized or specialized infant formula for conditions other than those for inborn errors of metabolism,
- Weight-loss foods and formula (products to aid weight loss).

Oregon

Oregon state statute 743A.070 mandates benefit coverage for a nonprescription elemental enteral formula for home use, if the formula is medically necessary for the treatment of severe intestinal malabsorption and a physician has issued a written order for the formula and the formula comprises the sole source, or an essential source, of nutrition. More information can be found at the following link: http://www.oregonlaws.org/ors/743A.070. Accessed January, 2016.

Washington

Effective for health benefit plans that are issued or renewed after December 31, 2015, Washington state statute (HB 2153) requires plans to coverage for medically necessary elemental formula, regardless of delivery method, when a provider diagnoses a patient with eosinophilic gastrointestinal associated disorders and orders and supervises the use of the elemental formula. More information can be found at the following link: http://apps.leg.wa.gov/documents/billdocs/2013-

14/Pdf/Bill%20Reports/House/2153%20HBA%20HCW%2014.pdf. Accessed January, 2016.

Eligible nutritional support expenses could be reimbursed using the Medical benefits, under Infusion, Medical Supply, Home Health or Medical Equipment and supply benefits depending on the design of the individual member's contract.

Nutritional support for complications of non-covered services such as bariatric surgery may be excluded by the member contract.

Rationale

[TOP]

This policy was originally developed in 1998 and literature searches have been conducted on a regular basis, the most recent in January, 2016

References

[TOP]

1. Reference MD – Medical Information from National Library of Medicine 2012 Medical Subject Headings, National Institutes of Health Unified Medical Language System. http://www.reference.md/files/D004/mD004750.html. Accessed January, 2016.
2. Poulia KA. Enteral Nutrition. In: Katsilambros, N, ed. *Clinical Nutrition in Practice.* EBSCO Publishing via HEAL-WA: Wiley=Blackwell; 2010: Chapter 17, 197-204.
3. Sundaram SS, Hoffenberg EJ, Kramer RE, Sondheimer JM, Furuta GT. Chapter 21. Gastrointestinal Tract. In: Hay WW, Jr, Levin MJ, Deterding RR, Abzug MJ, Sondheimer JM. eds. *CURRENT Diagnosis & Treatment: Pediatrics, 21e*. New York: McGraw-Hill; 32012. http://accessmedicine.mhmedical.com.proxy.heal-wa.org/content.aspx?bookid=497&Sectionid=40851688. Accessed January, 2016.
4. Zio L, Rothenberg ME, Immunology and Allergy Clinics of North America. Volume 27, Issue 3 , 443-455, August 2007.
5. Shifflet A, Forouhar F, Wu G. Eosinophilic Digestive Disease: Eosinophilic Esophagitis, Gastroenteritis, and Colitis. J Formos Med Assoc. 2009; 108(11):834-843. PMID 19933026
6. Policy reviewed by practicing pediatrician in 2007, 2008, 2009, 2010, 2011, 2012, 2013.

Coding

[TOP]

Codes	Number	Description
CPT	44015	Tube or needle jejunostomy for enteral alimentation, intraoperative, any method (List separately in addition to primary procedure)
HCPCS	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
	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
	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
	B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber,

	administered through an enteral feeding tube, 100 calories = 1 unit
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
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
B4159	Enteral formula, for pediatrics, nutritionally 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
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
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
B9000	Enteral nutrition infusion pump – without alarm
B9002	Enteral nutrition infusion pump – with alarm
B9004	Parenteral nutrition infusion pump, portable
B9006	Stationary
E9998	NOC for enteral supplies
E9999	NOC for parenteral supplies
S9434	Modified solid food supplements for inborn errors of metabolism
S9435	Medical foods for inborn errors of metabolism
S9340	Home therapy; enteral nutrition; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (enteral formula and nursing visits coded separately), per diem
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
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
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
Type of Service	Therapy

Appendix

[TOP]

N/A

History

[TOP]

Date	Reason
08/04/98	Add to Therapy Section - New Policy
03/02/99	Replace Policy - Policy and Policy Guidelines sections changed.
05/08/01	Replace Policy - Revised and updated.
05/14/02	Policy Deleted - Services will not be reviewed.
04/15/03	Policy Re-instated - Policy reviewed and updated. No change to the policy statement.
08/12/03	Replace Policy - Policy language clean-up only; no change to policy statement.
01/01/04	Replace Policy - CPT code updates only.
05/11/04	Replace Policy - Scheduled review, no changes to policy statement.
09/01/04	Replace Policy - Policy renumbered from PR.8.01.102. No changes to dates.
05/10/05	Replace Policy - Scheduled review; no changes to policy statement.
04/11/06	Replace Policy - Scheduled review; no changes to policy statement.
06/02/06	Disclaimer and Scope update - No other changes.
04/10/07	Replace Policy - Policy updated with literature review; reference added and codes updated. No change in policy statement.
07/08/08	Replace Policy - Policy updated with literature search; no change to the policy statement.
06/09/09	Replace Policy - Policy updated with literature search; no change to the policy statement.
08/11/09	Replace Policy - Allergic disorders addressed in the Policy Guidelines and Benefit Application as an OTC food source.
5/11/10	Replace Policy - Policy statement revised to restrict oral nutrition only for treatment of errors of inborn metabolism. TPN and EN policy statements reworded but intent is unchanged. Guidelines, Benefit Application and References updated. Title updated.
06/13/11	Replace Policy - Policy updated and reviewed by practicing pediatrician. No change to policy statement.
05/22/12	Replace policy. Policy updated and reviewed by practicing pediatrician. Minor edits for clarification. Policy statement unchanged.
05/28/13	Replace policy. Policy updated and reviewed by practicing pediatrician. No change to policy statement.
12/18/13	Update Related Policies. Modify title to 7.01.516.
05/02/14	Annual Review. Added two policy statements for WA and OR mandates. Removed policy statements, description, rationale and codes on TPN. References 1-5 added. Clarification added in Benefit application section. Policy title changed to "Home Enteral Nutrition".
02/25/15	Coding update. ICD-9 diagnosis and procedure codes removed; these were inadvertently reflected on the policy.
04/14/15	Annual Review. Clarification added in Policy Guidelines. Added table with IEM diagnosis, ICD-9 and ICD-10 codes.
05/27/15	Coding update. HCPCS codes S9434 and S9435 added.
11/20/15	Update Related Policies. Remove 7.01.516.
02/09/16	Annual Review. Policy reviewed. Policy statements unchanged.

ATTACHMENT

4

About Your Complaint and Appeal Rights

You can make complaints about:

- the care or service we provide
- the quality or availability of a healthcare service
- the care or service you get from any provider in our network.

You also have the right to appeal any action we take or decision we make about your coverage.

What if I need help understanding a denial?
Check your member booklet or benefits summary to understand what your plan does or does not cover. You can learn more about explanation of benefit notices or medical necessity on our website. If you still have questions, call Customer Service at 800-722-1471.

What if I don't agree with a decision my health plan makes?
You have the right to appeal such a decision within 180 days of the date you get notice of our decision.

How do I make a complaint?
Call Customer Service at 800-722-1471. The complaint process allows Customer Service to quickly and informally correct errors, clarify benefits or take steps to improve our service.

Customer Service may ask you to send your complaint for review through the formal internal appeals process outlined below.

How do I file an appeal?
Use our Member Appeal form, or send a letter to:

Premera Blue Cross
Attn: Member Appeals P.O. Box 91102
Seattle, WA 98111-9202

Or fax our Appeals Department at (425) 918-5592.

What if my situation is urgent?
If your provider thinks a delay will harm your health and we agree, we will speed up your review.

Who may file an appeal?
You or someone you choose to act for you may file an appeal. Complete the Appeals Authorization for Release of Healthcare Information and Records form if you want to have someone act for you.

Can I offer more information about my claim?
Yes, you may send us more information with your appeal submission.

Can I ask for copies of information related to my claim?
Yes, you may ask for copies by contacting us at 800-722-1471. There is no cost for these copies.

What happens next?
If you file an appeal, we will review our decision and send you a written response. If we continue to deny the payment, coverage or service request, we will send you information about further appeal rights, including those about independent review.

Resources to help you:
If you have questions about a denial of a claim or your appeal rights, contact Premera Customer Service for help at 800-722-1471. You may also get help from the Washington Consumer Assistance Program. If the Employee Retirement Income Security Act of 1974 (ERISA) governs your plan, you can also contact the Employee Benefits Security Administration of the U.S. Department of Labor.

Washington Consumer Assistance Program
5000 Capitol Blvd.
Tumwater, WA 98501
800-562-6900

www.insurance.wa.gov

Employee Benefits Security Administration
866-444-3272

If you have any questions, please call Customer Service at 800-722-1471.
Para obtener ayuda en español, llámenos al número de teléfono que se indica arriba.
Sa pagtamo ng tulong sa Tagalog, tawagan kami sa nasa itaas na numero ng telepono.
如果想用中文獲取幫助，請撥打上面的電話號碼聯繫我們.
Diné k'ehjí yáłti'ígíí shíka'adoolwoł nínízingo díí béésh bee hane'é bich'i'hodíílnih.
Our TDD/TTY number for the hearing-impaired is 800-842-5357.

PREMERA | BLUE CROSS
An Independent Licensee of the Blue Cross Blue Shield Association