

Department of Origin: Pharmacy	Effective Date: 12/06/2023
Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date approved: 12/06/2023
Pharmacy Clinical Policy Document: Vascular Endothelial Growth Factor Antagonists for Intravitreal Use	Replaces Effective Policy Dated: 2/15/2023
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PURPOSE:

The intent of the Vascular Endothelial Growth Factor Antagonists for Intravitreal Use Pharmacy Clinical Policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

Table 1: Preferred Biologics

Biologic	Molecule	Is this a Biosimilar?	Reference Product	HCPCS
Avastin	bevacizumab	N	N/A	J9035
Mvasi	bevacizumab-awwb	Y	Avastin	Q5107
Zirabev	bevacizumab-bvzr	Y	Avastin	Q5118
Alymsys	bevacizumab-maly	Y	Avastin	Q5126
Vegzelma	bevacizumab-adcd	Y	Avastin	Q5129

GUIDELINES:

Medical Necessity Criteria - Must satisfy any of the following: I - VII

I. Requests for *bevacizumab* – must satisfy all of the following: A and B

A. Must be ordered by an ophthalmologist; and

B. Member has one of the following indications: 1 - 7

1. Choroidal neovascularization, rare causes (such as but not limited to, degenerative myopia, idiopathic, angioid streaks, trauma, choroiditis, retinal dystrophies, ocular histoplasmosis); or
2. *Diabetic macular edema*; or
3. *Diabetic retinopathy*; or
4. Neovascular glaucoma and its aftereffects (rubeosis iridis); or
5. *Neovascular (wet) age-related macular degeneration (AMD)*; or
6. *Pseudoxanthoma elasticum (PXE)*; or

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7. Retinal vein occlusion (RVO) (such as, but not limited to, branch, central, tributary) and its aftereffects (retinal edema/cystoid macular edema).

Table 2: Non-Preferred Biologics

Biologics	Molecule	Is this a Biosimilar?	Reference Product	HCPCS
Beovu	brolocizumab-dbl	N	N/A	J0179
Byooviz	ranibizumab-nuna	Y	Lucentis	Q5124
Cimerli	ranibizumab-eqrn	Y	Lucentis	Q5128
Eylea	aflibercept	N	N/A	J0178
Lucentis	ranibizumab	N	N/A	J2778
Vabysmo	faricimab-svoa	N	N/A	J2777

II. Requests for Beovu – must satisfy all of the following: A - C

- A. Must be ordered by an ophthalmologist; and
- B. Member has one of the following indications: 1 or 2
 - 1. *Neovascular (wet) age-related macular degeneration (AMD)*; or
 - 2. *Diabetic Macular edema*; and
- C. Member has not responded to, is intolerant to, or is a poor candidate for *bevacizumab* (Table 1).

III. Requests for Byooviz – must satisfy all of the following: A – C

- A. Must be ordered by an ophthalmologist; and
- B. Member has one of the following indications: 1 - 3
 - 1. *Neovascular (wet) age-related macular degeneration (AMD)*; or
 - 2. Macular edema (fluid build-up) following retinal vein occlusion; or
 - 3. *Choroidal neovascularization, myopic*; and
- C. Member has not responded to, is intolerant to, or is a poor candidate for *bevacizumab* (Table 1).

II. Requests for Eylea – must satisfy one of the following: A – C, or D

- A. Must be ordered by an ophthalmologist; and

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- B. Member has one of the following indications: 1 - 4
 - 1. *Neovascular (wet) age-related macular degeneration (AMD)*; or
 - 2. Macular edema following retinal vein occlusion; or
 - 3. *Diabetic macular edema*; or
 - 4. *Diabetic retinopathy*; and
- C. Member has not responded to, is intolerant to, or is a poor candidate for *bevacizumab* (Table 1).
- D. Member has a diagnosis of retinopathy of prematurity

III. Requests for Cimerli or Lucentis – must satisfy all of the following: A - C

- A. Must be ordered by an ophthalmologist; and
- B. Member has one of the following indications: 1 - 5
 - 1. *Neovascular (wet) age-related macular degeneration (AMD)*; or
 - 2. Macular edema following retinal vein occlusion; or
 - 3. *Diabetic macular edema*; or
 - 4. *Diabetic retinopathy*; or
 - 5. *Choroidal neovascularization, myopic*; and
- C. Member has not responded to, is intolerant to, or is a poor candidate for *bevacizumab* (Table 1).

VI. Requests for Vabysmo – must satisfy all of the following: A - C

- A. Must be ordered by an ophthalmologist; and
- B. Member has one of the following indications: 1-3
 - 1. *Neovascular (wet) age-related macular degeneration (AMD)*; or
 - 2. *Diabetic macular edema*; or
 - 3. Macular edema following retinal vein occlusion; and
- C. Member has not responded to, is intolerant to, or is a poor candidate for *bevacizumab* (Table 1).

VII. Continuation request – Allow up to an additional 12 months

EXCLUSIONS:

The following are considered investigative (see Pharmacy Investigative List): I - II

- I. *Bevacizumab* for all ocular indications not covered in the *bevacizumab* section above.
- II. Lucentis for all ocular indications not covered in the Lucentis section above.

DEFINITIONS:

Age-related macular degeneration (AMD):

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A disease that causes blurring of your central vision. The blurring happens because of damage to the macula, a small area at the back of the eye. The macula helps you see the fine detail in things that your eyes are focusing on. Macular degeneration makes it harder to do things that require sharp central vision, like reading, driving, and recognizing faces. It does not affect side vision, so it does not lead to complete blindness.

There are two types of macular degeneration—wet and dry. The dry form is by far the most common type. The wet form is much less common, but it happens more quickly and is more severe.

Angiogenesis:

Development of new blood vessels

Biologic/biological:

Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

Bevacizumab:

Reference product or biosimilar

Choroidal neovascularization (CNV):

The creation of new blood vessels in the choroid layer of the eye. Choroidal neovascularization is a common cause of neovascular degenerative maculopathy, ie, 'wet' macular degeneration, commonly exacerbated by extreme myopia, malignant myopic degeneration, or age-related developments.

Diabetic Macular Edema (DME):

Swelling of the retina in diabetes mellitus due to leaking of fluid from blood vessels within the macula.

Diabetic Retinopathy:

Damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina). Caused by too much sugar in the blood, leading to blockage of the tiny blood vessels that nourish the retina, cutting off its blood supply.

Intravitreal:

Introduced in the clear jelly-like substance enclosed by a hyaloid membrane that fills the eyeball posterior to the lens

Myopia:

Nearsightedness

Neovascular AMD (wet):

A form of AMD where abnormal blood vessels found behind the retina proliferate.

Ocular Neovascularization:

Formation of blood vessels in the eye in an abnormal or excessive rate.

Pseudoxanthoma Elasticum (PXE):

Autosomal recessive disease manifested by several lesions in the eye

Vascular Endothelial Growth Factor (VEGF):

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A protein that stimulates the growth of vascular endothelial cells and plays an important role in *angiogenesis*.

BACKGROUND:

This clinical policy is based on U.S. Food and Drug Administration (FDA) approved indications, expert consensus opinion and/or available reliable evidence.

Vascular Endothelial Growth Factor (VEGF) stimulates the growth of vascular endothelial cells, which may lead to *Ocular Neovascularization*. Avastin (bevacizumab), Beovu (brolucizumab-dbl), Byooviz (ranibizumab-nuna), Eylea (aflibercept), Lucentis (ranibizumab), Macugen (pegaptanib), Mvasi (bevacizumab-awwb), Vabysmo (faricimab-svoa) and Zirabev (bevacizumab-bvzr) are VEGF antagonists that work by blocking the abnormal/excessive growth and leakage of blood vessels in the eye that may cause visual loss. Avastin was originally indicated for the treatment of colon/rectal cancer and was manufactured by the same company (Genentech) as Lucentis, although, Avastin has been used off-label in the recent years as a VEGF antagonist for *Ocular Neovascularization*. Data from the Comparisons of Age-Related Macular Degeneration Treatment Trials (CATT) show that Avastin and Lucentis are equivalent in their ability to improve visual acuity.

Bevacizumab is supplied in sterile vials containing a solution of 25 mg/mL. Doses utilized in ophthalmic conditions generally range from 6.2 mcg to 2.5 mg. Therefore, bevacizumab in vials is often divided into single-dose, prefilled syringes for intravitreal use by compounding pharmacies. Compounding pharmacies must comply with United States Pharmacopeia (USP) Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP). The Pharmacy Compounding Accreditation Board can verify that the pharmacy is adhering to these standards.

Prior Authorization: Yes, per network provider agreement - initial authorize for up to 12 months; continued use, authorize for up to 24 months. This is subject to the member's contract benefits.

CODING: HCPCS - 2023

C9142 Injection, bevacizumab-maly, biosimilar, 10 mg (Alymsys)
J0178 Injection, aflibercept 1 mg (Eylea)
J0179 Injection, brolucizumab-dbl, 1mg (Beovu)
J2777 Injection, faricimab-svoa, 0.1 mg (Vabysmo)
J2778 Injection, ranibizumab, 0.1mg (Lucentis)
Q5128 Injection, ranibizumab-eqrn, biosimilar, 0.1 mg (Cimerli)
J9035 Injection, bevacizumab, 10mg (Avastin)
Q5107 Injection, bevacizumab-awwb, biosimilar 10 mg (Mvasi)
Q5118 Injection, bevacizumab-bvzr, biosimilar 10 mg (Zirabev)
Q5124 Injection, ranibizumab-nuna, biosimilar, 0.1 mg (Byooviz)
Q5129 Injection, bevacizumab-adcd, biosimilar, 10 mg (Vegzelma)

ICD-10 Codes covered if indications are met for Avastin, Alymsys, Mvasi and Zirabev
E08.311, E08.3211, E08.3212, E08.3213, E08.3311, E08.3312, E08.3313, E08.3411, E08.3412, E08.3413, E08.3511, E08.3512, E08.3513, E08.3521, E08.3522, E08.3523, E08.3531, E08.3532,

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E08.3533, E08.3541, E08.3542, E08.3543, E08.3551, E08.3552, E08.3553, E08.3591, E08.3592, E08.3593, E09.311, E09.3211, E09.3212, E09.3213, E09.3311, E09.3312, E09.3313, E09.3411, E09.3412, E09.3413, E09.3511, E09.3512, E09.3513, E09.3521, E09.3522, E09.3523, E09.3531, E09.3532, E09.3533, E09.3541, E09.3542, E09.3543, E09.3551, E09.3552, E09.3553, E09.3591, E09.3592, E09.3593, E10.311, E10.3211, E10.3212, E10.3213, E10.3311, E10.3312, E10.3313, E10.3411, E10.3412, E10.3413, E10.3511, E10.3512, E10.3513, E10.3521, E10.3522, E10.3523, E10.3531, E10.3532, E10.3533, E10.3541, E10.3542, E10.3543, E10.3551, E10.3552, E10.3553, E10.3591, E10.3592, E10.3593, E11.311, E11.3211, E11.3212, E11.3213, E11.3311, E11.3312, E11.3313, E11.3411, E11.3412, E11.3413, E11.3511, E11.3512, E11.3513, E11.3521, E11.3522, E11.3523, E11.3531, E11.3532, E11.3533, E11.3541, E11.3542, E11.3543, E11.3551, E11.3552, E11.3553, E11.3591, E11.3592, E11.3593, E13.311, E13.3211, E13.3212, E13.3213, E13.3311, E13.3312, E13.3313, E13.3411, E13.3412, E13.3413, E13.3511, E13.3512, E13.3513, E13.3521, E13.3522, E13.3523, E13.3531, E13.3532, E13.3533, E13.3541, E13.3542, E13.3543, E13.3551, E13.3552, E13.3553, E13.3591, E13.3592, E13.3593, H21.1X1, H21.1X2, H21.1X3, H21.1X9, H34.8110, H34.8111, H34.8112, H34.8120, H34.8121, H34.8122, H34.8130, H34.8131, H34.8132, H34.8310, H34.8311, H34.8312, H34.8320, H34.8321, H34.8322, H34.8330, H34.8331, H34.8332, H35.051, H35.052, H35.053, H35.059, H35.3210, H35.3211, H35.3212, H35.3213, H35.3220, H35.3221, H35.3222, H35.3223, H35.3230, H35.3231, H35.3232, H35.3233, H35.351, H35.352, H35.353, H35.359, H35.81, H40.89, H44.2A1, H44.2A2, H44.2A3

ICD-10 Codes covered if indications are met for Beovu

H35.3210, H35.3211, H35.3212, H35.3213, H35.3220, H35.3221, H35.3222, H35.3223, H35.3230, H35.3231, H35.3232, H35.3233

ICD-10 Codes covered if indications are met for Eylea

E08.311, E08.319, E08.3211, E08.3212, E08.3213, E08.3291, E08.3292, E08.3293, E08.3311, E08.3312, E08.3313, E08.3391, E08.3392, E08.3393, E08.3411, E08.3412, E08.3413, E08.3491, E08.3492, E08.3493, E08.3511, E08.3512, E08.3513, E08.3521, E08.3522, E08.3523, E08.3531, E08.3532, E08.3533, E08.3541, E08.3542, E08.3543, E08.3551, E08.3552, E08.3553, E08.3591, E08.3592, E08.3593, E09.311, E09.319, E09.3211, E09.3212, E09.3213, E09.3291, E09.3292, E09.3293, E09.3311, E09.3312, E09.3313, E09.3391, E09.3392, E09.3393, E09.3411, E09.3412, E09.3413, E09.3491, E09.3492, E09.3493, E09.3511, E09.3512, E09.3513, E09.3521, E09.3522, E09.3523, E09.3531, E09.3532, E09.3533, E09.3541, E09.3542, E09.3543, E09.3551, E09.3552, E09.3553, E09.3591, E09.3592, E09.3593, E10.311, E10.319, E10.3211, E10.3212, E10.3213, E10.3291, E10.3292, E10.3293, E10.3311, E10.3312, E10.3313, E10.3391, E10.3392, E10.3393, E10.3411, E10.3412, E10.3413, E10.3491, E10.3492, E10.3493, E10.3511, E10.3512, E10.3513, E10.3521, E10.3522, E10.3523, E10.3531, E10.3532, E10.3533, E10.3541, E10.3542, E10.3543, E10.3551, E10.3552, E10.3553, E10.3591, E10.3592, E10.3593, E11.311, E11.319, E11.3211, E11.3212, E11.3213, E11.3291, E11.3292, E11.3293, E11.3311, E11.3312, E11.3313, E11.3391, E11.3392, E11.3393, E11.3411, E11.3412, E11.3413, E11.3491, E11.3492, E11.3493, E11.3511, E11.3512, E11.3513, E11.3521, E11.3522, E11.3523, E11.3531, E11.3532, E11.3533, E11.3541, E11.3542, E11.3543, E11.3551, E11.3552, E11.3553, E11.3591, E11.3592, E11.3593, E13.311, E13.319, E13.3211, E13.3212, E13.3213, E13.3291, E13.3292, E13.3293, E13.3311, E13.3312, E13.3313, E13.3391, E13.3392, E13.3393, E13.3411, E13.3412, E13.3413, E13.3491, E13.3492, E13.3493, E13.3511, E13.3512, E13.3513, E13.3521, E13.3522, E13.3523, E13.3531, E13.3532, E13.3533, E13.3541, E13.3542, E13.3543, E13.3551, E13.3552, E13.3553, E13.3591, E13.3592, E13.3593, H34.8110, H34.8111, H34.8112, H34.8120, H34.8121, H34.8122, H34.8130, H34.8131, H34.8132, H34.8310, H34.8311, H34.8312, H34.8320, H34.8321, H34.8322, H34.8330, H34.8331, H34.8332, H35.3210, H35.3211, H35.3212, H35.3213, H35.3220, H35.3221, H35.3222, H35.3223, H35.3230, H35.3231, H35.3232, H35.3233, H35.351, H35.352, H35.353, H35.81

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ICD-10 Codes covered if indications are met for Lucentis and Byooviz

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ICD-10 Codes covered if indications are met for Vabysmo

E08.311, E08.3211, E08.3212, E08.3213, E08.3311, E08.3312, E08.3313, E08.3411, E08.3412, E08.3413, E08.3511, E08.3512, E08.3513, E09.311, E09.3211, E09.3212, E09.3213, E09.3311, E09.3312, E09.3313, E09.3411, E09.3412, E09.3413, E09.3511, E09.3512, E09.3513, E10.311, E10.3211, E10.3212, E10.3213, E10.3311, E10.3312, E10.3313, E10.3411, E10.3412, E10.3413, E10.3511, E10.3512, E10.3513, E11.311, E11.3211, E11.3212, E11.3213, E11.3311, E11.3312, E11.3313, E11.3411, E11.3412, E11.3413, E11.3511, E11.3512, E11.3513, E13.311, E13.319, E13.3211, E13.3212, E13.3213, E13.3311, E13.3312, E13.3313, E13.3411, E13.3412, E13.3413, E13.3511, E13.3512, E13.3513, H35.3210, H35.3211, H35.3212, H35.3213, H35.3220, H35.3221, H35.3222, H35.3223, H35.3230, H35.3231, H35.3232, H35.3233

REFERENCES

1. Aylmsys [package insert] Bridgewater, NJ; Amneal Pharmaceuticals LLC; 2022.
2. Avastin [package insert] San Francisco, CA; Genentech, Inc.; 2022.
3. Beovu [package insert] East Hanover, NJ; Novartis Pharmaceuticals Corporation.; 2023.
4. Byooviz [package insert] Cambridge MA; Biogen, Inc.; 2023
5. Eylea [package insert] Tarrytown, NY; Regeneron Pharmaceuticals, Inc.; 2023.
6. Lucentis [package insert] San Francisco, CA; Genentech, Inc.; 2023.
7. Mvasi [package insert] Thousand Oaks, CA; Amgen Inc.; 2023.
8. Vabysmo [package insert] San Francisco, CA; Genentech, Inc.; 2023.

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Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).