

MEDICAL POLICY – 7.01.83

Auditory Brainstem Implant

BCBSA Ref. Policy: 7.01.83

Effective Date: May 1, 2024

Last Revised: April 8, 2024

Replaces: N/A

RELATED MEDICAL POLICIES:


7.01.84 Semi-Implantable and Fully Implantable Middle Ear Hearing Aids

7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids

7.01.586 Cochlear Implant

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [DOCUMENTATION REQUIREMENTS](#) | [CODING](#)
[RELATED INFORMATION](#) | [EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

Introduction

Neurofibromatosis type 2 is an inherited condition. It causes noncancerous tumors to grow on nerves. The usual location of these tumors is on the auditory nerves. These nerves transmit information from the inner ear to the brain and allow us to hear. Removing neurofibromatosis type 2 tumors can damage the auditory nerve, leading to deafness. An auditory brainstem implant is a device that transmits sound directly to the brainstem. The implant has two parts: the processor, which is worn near the ear, and a surgically implanted electrode. A microphone picks up sound and the processor turns the sound waves into electrical signals. The electrical signals are sent to an electrode near the brain stem. Medical studies show that auditory brainstem implants are successful in people whose hearing was damaged by surgery to remove tumors that were specifically caused by neurofibromatosis type 2. Using auditory brainstem implants has also been proposed to treat deafness from other types of tumors or other conditions. More studies are needed to see if auditory brainstem implants work for conditions other than neurofibromatosis type 2.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Implant	Medical Necessity
Unilateral use of an auditory brainstem implant	<p>Unilateral use of an auditory brainstem implant (using surface electrodes on the cochlear nuclei) may be considered medically necessary when ALL of the following criteria are met:</p> <ul style="list-style-type: none"> • The individual has neurofibromatosis type 2 • Age 12 years or older • The individual became deaf because of bilateral resection of neurofibromas of the auditory nerve. <p>An auditory brainstem implant is considered investigational for all other conditions including non-neurofibromatosis type 2 indications.</p>

Implant	Investigational
Bilateral use of an auditory brainstem implant	Bilateral use of an auditory brainstem implant is considered investigational.
Penetrating electrode auditory brainstem implant (PABI)	Penetrating (vs. surface electrodes on the cochlear nuclei) electrode auditory brainstem implant is considered investigational.

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain relevant history and physical supporting:
 - Diagnosis of neurofibromatosis type 2 (the tumors are commonly called vestibular schwannomas or acoustic neuromas)
 - That the member is completely deaf due to surgical removal of neurofibromas on the auditory nerve of both ears

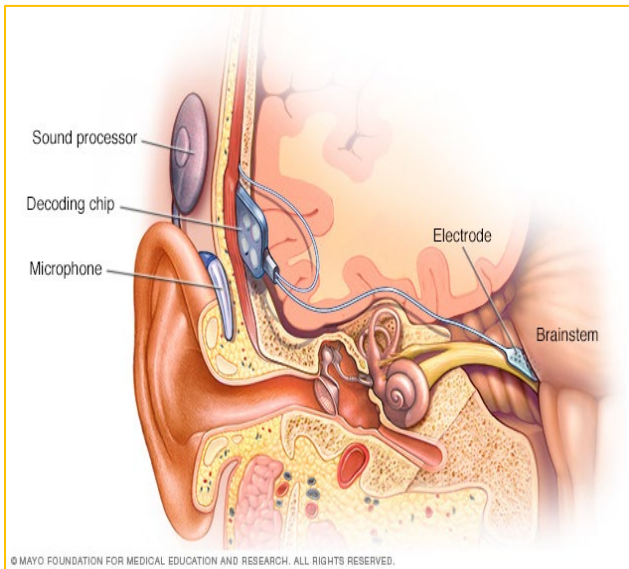
Coding



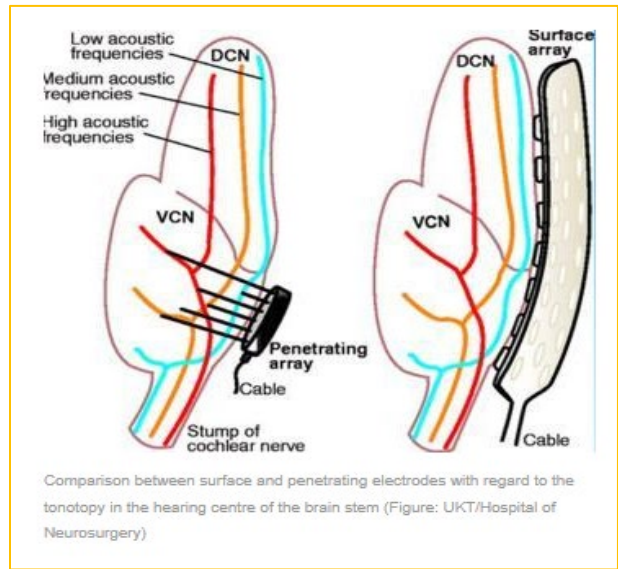
Code	Description
CPT	
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour
HCPCS	
S2235	Implantation of auditory brain stem implant

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information



Source: <https://www.mayoclinic.org/tests-procedures/auditory-brainstem-implant/about/pac-20384649> Accessed March 24, 2023



Source: <http://www.regmed.uni-tuebingen.de/?q=en/a-difficult-nut-to-crack-regeneration-in-the-central-nervous-system> Resource Archived.

Definition of Terms

Neurofibromatosis type 2 (NF2): A rare hereditary condition commonly associated with bilateral vestibular schwannomas, which are benign tumors that occur on the nerves of the inner ear and cause loss of hearing and balance. These tumors are also known as acoustic neuromas.

Consideration of Age

The age listed in the policy statement is based on US Food and Drug Administration approval of the auditory brainstem implant device for ages 12 and older.

Evidence Review

Description

An auditory brainstem implant (ABI) is designed to restore some hearing in people with neurofibromatosis type 2 (NF2) who are rendered deaf by bilateral removal of neurofibromas involving the auditory nerve. ABIs have also been studied to restore hearing for other non-neurofibromatosis indications.

Background

The ABI is intended to restore some hearing in people with NF2 who are rendered deaf by bilateral removal of the characteristic neurofibromas involving the auditory nerve. The ABI consists of an externally worn speech processor that provides auditory information by electrical signal that is transferred to a receiver/stimulator implanted in the temporal bone. The receiver/stimulator is, in turn, attached to an electrode array implanted on the surface of the cochlear nerve in the brainstem, thus bypassing the inner ear and auditory nerve. The electrode stimulates multiple sites on the cochlear nucleus, which is then processed normally by the brain. To place the electrode array on the surface of the cochlear nucleus, the surgeon must be able to visualize specific anatomic landmarks. Because large neurofibromas compress the brainstem and distort the underlying anatomy, it can be difficult or impossible for the surgeon to correctly place the electrode array. For this reason, individuals with large, long-standing tumors may not benefit from the device.¹

ABIs are also being studied to determine whether they can restore hearing for other non-neurofibromatosis causes of hearing impairment in adults and children, including absence of or trauma to the cochlea or auditory nerve. It is estimated that 1.7 per 100,000 children are affected by bilateral cochlea or cochlear nerve aplasia and 2.6 per 100,000 children are affected by bilateral cochlea or cochlear nerve hypoplasia.²



Summary of Evidence

For individuals who are deaf due to bilateral resection of neurofibromas of the auditory nerve who receive an auditory brainstem implant (ABI), the evidence includes a large, prospective case series and a technology assessment that included observational studies. The relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. The technology assessment found the highest quality evidence for improvement in hearing function, but evidence on other outcomes was lacking. The US Food and Drug Administration (FDA) approval of the Nucleus 24 device in 2000 was based on a prospective case series of 90 individuals 12 years of age or older, of whom 60 had the implant for at least three months. From this group, 95% had a significant improvement in lip reading or improvement on sound-alone tests. While use of an ABI is associated with a very modest improvement in hearing, this level of improvement is considered significant for those individuals who have no other treatment options. A systematic review of 16 studies found that ABI was associated with improved sound recognition and speech perception. Based on these results, ABIs are considered appropriate for the individual population age ≥ 12 years with NF2 and deafness following tumor removal. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are deaf due to nontumor etiologies who receive an ABI, the evidence includes case series and systematic reviews of case series. The relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. In general, ABIs have not demonstrated hearing benefits over cochlear implants for many conditions not related to NF2, and some older (now obsolete) ABI models have been associated with high rates of device failure and adverse events in this population. In addition, ABI studies have shown inferior outcomes in children with other disabilities. However, ABIs hold promise for select individuals when the cochlea or cochlear nerve is absent. Evaluation is currently ongoing with the recently available Nucleus ABI541 to determine its efficacy and durability in children. Thus, further study is also needed to define populations that would benefit from these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in [Table 1](#).



Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05810220	Investigating Auditory Processing in the Users of Auditory Brainstem and Cochlear Implants	200	Apr 2024
NCT02310399	Auditory Brainstem Implant (ABI) in Children With No Cochleae or Auditory Nerves	20	May 2027
NCT02630589	Implantation of an Auditory Brainstem Implant for the Treatment of Incapacitating Unilateral Tinnitus	10	Jan 2026
Unpublished			
NCT01904448	An Early Feasibility Study of the Safety and Efficacy of the Nucleus 24 Auditory Brainstem Implant in Children With Cochlear or Cochlear Nerve Disorders Not Resulting From Neurofibromatosis Type II	5	Oct 2017

IRB: Institutional Review Board; NCT: national clinical trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute Health and Care Excellence

In 2005, NICE issued guidance on interventional procedures for auditory brainstem implants.¹⁷ The guidance stated: "...evidence on safety and efficacy of auditory brain stem implants appears adequate to support the use of this procedure by surgical teams experienced in this technique."



Medicare National Coverage

There is no national coverage determination. The Medicare Benefit Policy Manual references hearing aids and auditory implants, stating that hearing aids are excluded from coverage, including air-conduction and bone-conduction devices. However, devices that produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve are payable by Medicare as prosthetic devices. These devices are indicated only when hearing aids are medically inappropriate or cannot be used. Along with cochlear and auditory brainstem implants, the benefit manual specifically refers to osseointegrated implants as prosthetic devices.

Regulatory Status

In 2000, the Nucleus 24 Auditory Brainstem Implant System (Cochlear Corp.) was approved by the FDA through the premarket approval process. The speech processor and receiver are similar to the devices used in cochlear implants; the electrode array placed on the brainstem is the novel component of the device. The device is indicated for individuals 12 years of age or older who have been diagnosed with NF2. The Nucleus 24 Auditory Brainstem Implant System approval was based on the efficacy study of unilateral implants either at first-side or second-side tumor removal surgery.¹ The Nucleus 24 is now obsolete.

In June 2016, the Nucleus ABI541 Auditory Brainstem Implant (Cochlear Corp.) was approved by the FDA through a supplement to the premarket approval for the Nucleus 24. The new implant is indicated for individuals 12 years of age or older who have been diagnosed with NF2.³

FDA product code: MCM.

References

1. Food and Drug Administration. Nucleus 24 Auditory Brainstem Implant System. FDA Summary of Safety and Effectiveness. 2000; https://www.accessdata.fda.gov/cdrh_docs/pdf/P000015B.pdf. Accessed March 25, 2024.
2. Kaplan AB, Kozin ED, Puram SV, et al. Auditory brainstem implant candidacy in the United States in children 0-17 years old. *Int J Pediatr Otorhinolaryngol*. Mar 2015; 79(3): 310-315. PMID 25577282



3. Food and Drug Administration. Premarket Approval (PMA). Nucleus ABI541 Auditory Brainstem Implant. 2016. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000015S012>. Accessed March 25, 2024.
4. Ebinger K, Otto S, Arcaroli J, et al. Multichannel auditory brainstem implant: US clinical trial results. *J Laryngol Otol Suppl.* 2000; (27): 50-3. PMID 11211440
5. Otto SR, Shannon RV, Wilkinson EP, et al. Audiologic outcomes with the penetrating electrode auditory brainstem implant. *Otol Neurotol.* Dec 2008; 29(8): 1147-54. PMID 18931643
6. Ontario Health (Quality). Auditory brainstem implantation for adults with neurofibromatosis 2 or severe inner ear abnormalities: a health technology assessment. *Ont Health Technol Assess Ser [Internet].* 2020 Mar;20(4): 185. <https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/auditory-brainstem-implantation-for-adults-with-neurofibromatosis-2-or-severe-inner-ear-abnormalities>. Accessed March 25, 2024.
7. Merkus P, Di Lella F, Di Trapani G, et al. Indications and contraindications of auditory brainstem implants: systematic review and illustrative cases. *Eur Arch Otorhinolaryngol.* Jan 2014; 271(1): 3-13. PMID 23404468
8. Medina M, Di Lella F, Di Trapani G, et al. Cochlear implantation versus auditory brainstem implantation in bilateral total deafness after head trauma: personal experience and review of the literature. *Otol Neurotol.* Feb 2014; 35(2): 260-70. PMID 24448286
9. Noij KS, Kozin ED, Sethi R, et al. Systematic Review of Nontumor Pediatric Auditory Brainstem Implant Outcomes. *Otolaryngol Head Neck Surg.* Nov 2015; 153(5): 739-50. PMID 26227469
10. Colletti L, Wilkinson EP, Colletti V. Auditory brainstem implantation after unsuccessful cochlear implantation of children with clinical diagnosis of cochlear nerve deficiency. *Ann Otol Rhinol Laryngol.* Oct 2013; 122(10): 605-12. PMID 24294682
11. Sennaroğlu L, Sennaroğlu G, Yücel E, et al. Long-term Results of ABI in Children With Severe Inner Ear Malformations. *Otol Neurotol.* Aug 2016; 37(7): 865-72. PMID 27273392
12. Sennaroglu L, Ziyal I, Atas A, et al. Preliminary results of auditory brainstem implantation in prelingually deaf children with inner ear malformations including severe stenosis of the cochlear aperture and aplasia of the cochlear nerve. *Otol Neurotol.* Sep 2009; 30(6): 708-15. PMID 19704357
13. Colletti V, Carner M, Miorelli V, et al. Auditory brainstem implant (ABI): new frontiers in adults and children. *Otolaryngol Head Neck Surg.* Jul 2005; 133(1): 126-38. PMID 16025066
14. Colletti V. Auditory outcomes in tumor vs. nontumor patients fitted with auditory brainstem implants. *Adv Otorhinolaryngol.* 2006; 64: 167-185. PMID 16891842
15. Colletti L. Beneficial auditory and cognitive effects of auditory brainstem implantation in children. *Acta Otolaryngol.* Sep 2007; 127(9): 943-6. PMID 17712673
16. Colletti V, Shannon RV, Carner M, et al. Complications in auditory brainstem implant surgery in adults and children. *Otol Neurotol.* Jun 2010; 31(4): 558-64. PMID 20393378
17. National Institute Health and Care Excellence (NICE). Auditory brain stem implants [IPG108]. 2005. <https://www.nice.org.uk/guidance/ipg108>. Accessed March 25, 2024.

History

Date	Comments
05/01/18	New policy, approved April 10, 2018, effective August 3, 2018. Add to Surgery section. This policy was previously archived but it is now being reinstated. Unilateral use of an



Date	Comments
	auditory brainstem implant may be considered medically necessary when criteria are met, considered investigational for all other conditions. PABI and Bilateral use of an auditory brainstem implant are considered investigational. Image added. Added definition for neurofibramotosis type 2.
09/21/18	Minor update. Added Consideration of Age information.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through December 2018; no references added. Policy statements unchanged.
05/01/20	Annual Review, approved April 7, 2020. Policy updated with literature review through December 2019; reference added and section summary for neurofibromas added. Policy statements unchanged
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through January 11, 2021; references added. Policy statements unchanged.
05/01/22	Annual Review, approved April 11, 2022. Policy updates with literature review through December 16, 2021; no references added. Policy statements unchanged.
05/01/23	Annual Review, approved April 10, 2023. Policy updates with literature review through January 3, 2023; no references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/15/23	Updated Related Policies. 7.01.03 is replaced by 7.01.547 Implantable Bone Conduction and Bone-Anchored Hearing Aids and 7.01.05 is replaced with 7.01.586 Cochlear Implant.
05/01/24	Annual Review, approved April 8, 2024. Policy updates with literature review through December 18, 2023; no references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

Scope: 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.





Discrimination is Against the Law

LifeWise Health Plan of Washington (LifeWise) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. LifeWise does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. LifeWise provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). LifeWise provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that LifeWise has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator — Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-6396, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@LifeWiseHealth.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights 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 Ave 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>. You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx>.

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-817-3056 (TTY: 711).

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 800-817-3056 (TTY: 711)。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-817-3056 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-817-3056 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-817-3056 (телетайп: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-817-3056 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки.

Телефонуйте за номером 800-817-3056 (телетайп: 711).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតលុយ គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 800-817-3056 (TTY: 711)។

注意事項: 日本語を話される場合、無料の言語支援をご利用いただけます。800-817-3056 (TTY:711) まで、お電話にてご連絡ください。

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያገለግሉት ተዘጋጅተዋል። ወደ ሚከተለው ቁጥር ይደውሉ 800-817-3056 (መስማት ለተሳናቸው: 711)።

XIYYEEFFANNA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-817-3056 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-817-3056 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-817-3056 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-817-3056 (TTY: 711).

ໂປດອຸບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ຄ່າສົ່ງຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 800-817-3056 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sévis èd pou lang ki disponib gratis pou ou. Rele 800-817-3056 (TTY: 711).

ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-817-3056 (ATS : 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-817-3056 (TTY: 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-817-3056 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-817-3056 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-817-3056 (TTY: 711) تماس بگیرید.