Department of Origin: Integrated Healthcare Services	**Effective Date:** 11/11/24
Approved by: Chief Medical Officer	**Date Approved:** 10/17/24
Clinical Policy Document: Levels of Evidence (LOE) and the Evaluation of Health Care Services	**Replaces Effective Clinical Policy Dated:** 09/12/23
Reference #: MP/L004	**Page:** 1 of 13

PURPOSE:
The intent of this clinical policy is to outline the processes for evaluating *medical literature* and its evidence rating, where available, to ensure inclusion in benefit coverage for new technology or application of existing technology of a *health care service* is based on *reliable evidence*.

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:
The Plan routinely assesses *medical literature* to determine if new technology or application of existing technology associated with a *health care service* is proven effective by *reliable evidence*.
This includes *medical literature* reflecting a high level of evidence showing safety and effectiveness and positive effects on health outcomes will be considered for inclusion in benefit coverage.

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.

COVERAGE:

I. The following categories will be assessed for evidence ratings demonstrating that a *health care service* is proven effective by *reliable evidence*, none of the categories shall be determinative by itself.

   A. Advisory Committee on Immunization Practices (ACIP) - Affirmative recommendation for routine use

   B. Government registry agencies (eg, U.S. Food and Drug Administration [FDA]) – Assessment of risk of safety and effectiveness based on the associated development, classification and approval pathways.
      1. *Drug development* and approval pathway considerations
         a. Development designations
            1) Fast track
            2) *Breakthrough therapy*
            3) Priority review
         b. Approval pathways
            1) Standard
            2) *Accelerated approval*

      2. Device development, *classification* and approval pathway considerations. Medical devices approved via the FDA Premarket Notification [*510(k)]* pathway must be supported by *reliable evidence*.
         a. Classifications
            1) *Class 1*
            2) *Class 2*
            3) *Class 3*

b. Approval pathways
   1) Least regulatory control (most exempt from premarket submission) – Class I
   2) Premarket Notification [*510(k)*] – Class II
   3) *Premarket Approval* Application [PMA]) - Class III
   4) De Novo – device types that have never been marketed in the U.S., but whose safety profile and technology are now reasonably well understood
   5) Humanitarian Device Exemption (HDE) – devices for orphan disease; intended to benefit patients in diagnosis and/or treatment of disease or condition affecting or manifested in fewer than 4,000 patients per year in the U.S.

C. National Comprehensive Cancer Network (NCCN) Guidelines – Category must be 1, 2A, or 2B (see Attachment B)

D. *Authoritative Compendia*
   1. American Hospital Formulary Service- Drug Information (AHFS-DI) – narrative text is supportive

   2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium - Category must be 1, 2A, or 2B (see Attachment B)

   3. Micromedex DrugDex – Category must be Class I, Class IIA, Class IIB

   4. Clinical Pharmacology – narrative text is supportive

   5. Lexi-Drugs – indication is listed as Use: Off-label and rated as Evidence Level A

E. Specialty/Professional Society Guidelines and Clinical Criteria (eg, ACOG, ACMG, ADA, etc.) - Recommendation must be based on be moderate or high level of evidence as demonstrated by “should” or “will/is” statements

F. Technology Assessment Bodies reports, such as, but not limited to Hayes, Inc.
   1. Rating must be A or B (see Attachment C); or

   2. Clinical Studies or Systematic Reviews: Level of Support must be Moderate or Substantial; or

   3. Clinical Practice Guidelines and Position Statements must have Strong Support for the Technology.

G. United States Preventive Services Task Force (USPSTF) – Grade must be A or B (see Attachment D)

H. Point of Care Synthesized Resources
   1. DynaMed - Rating must be a Level of Evidence 1 (see Attachment E)

   2. UpToDate - Recommendation must be strong (Grade 1A, 1B or 1C) as demonstrated by “we recommend” statements

II. Categories that do not have an evidence rating must have a LOE equal to 1 or 2 and a Strength of Recommendation (SOR) equal to A or B, based on the Oxford Centre for Evidence-Based Medicine (OECBM) LOE and the American Academy of Family Physicians (AAFP) Strength-of-Recommendation Taxonomy (SORT). Categories include, such as but not limited to the following:

A. Agency for Healthcare Research and Quality (AHRQ)

B. Clinical Trial Committee Reports

C. Expert consensus opinions (eg, external local or national providers, etc.)

D. The National Library of Medicine (NLM)

E. Published, peer-reviewed medical journal articles that include a systematic review and either a traditional meta-analysis or a *network meta-analysis* (see Attachment A)

F. *Randomized controlled trials* (RCTs) that are adequately powered to provide a true assessment of causality and are without methodological defects – including, but not limited to the following:
   a. Have generalizability to the population being studied
   b. Include intention-to-treat (ITT) analysis (ie, subjects analyzed in the groups to which they were randomized) versus per protocol analysis (ie, only participants who completed the treatment originally allocated are analyzed)

DEFINITIONS:

510(k):
Requires proof that the devices is *substantially equivalent* (SE) to a legally marketed device that is not subject to Premarket Approval (PMA)

Accelerated Approval:
Can be applied to promising therapies that treat a serious or life-threatening condition and provide therapeutic benefit over available therapies. This approach allows for the approval of a drug that demonstrates an effect on a "surrogate endpoint" that is reasonably likely to predict clinical benefit, or on a clinical endpoint that occurs earlier but may not be as robust as the standard endpoint used for approval. After the drug enters the market, the drug maker is required to conduct post-marketing clinical trials to verify and describe the drug's benefit. If further trials fail to verify the predicted clinical benefit, FDA may withdraw approval.

Authoritative Compendia:
American Hospital Formulary Service- Drug Information (AHFS-DI), National Comprehensive Cancer Network, (NCCN) Drugs and Biologics Compendium, Micromedex DrugDex, or Clinical Pharmacology, and Lexi-Drugs

Drug Development Pathways:
- Fast Track - A process designed to facilitate the development and advance the review of drugs that treat serious conditions, and fill an unmet medical need, based on promising animal or human data. Fast tracking can get important new drugs to the patient earlier.
- Breakthrough Therapy - This designation expedites the development and review of drugs that are intended to treat a serious condition, and preliminary clinical evidence indicates that the drug may

demonstrate substantial improvement over available therapy. A drug with Breakthrough Therapy designation is also eligible for the Fast Track process.

- Priority Review - The FDA aims to take action on an application within six months, compared to 10 months under standard review. A Priority Review designation directs attention and resources to evaluate drugs that would significantly improve the treatment, diagnosis, or prevention of serious conditions.

Device Classifications:

- Class 1 devices pose the least amount of risk to consumers. These low-risk devices, such as oxygen masks or surgical tools, are subject to "general controls." General controls ensure the safety and effectiveness of devices once they're manufactured. General controls consider the following factors:
  - Good manufacturing practices
  - Standards and Reporting Adverse Events to FDA
  - registration,
  - general recordkeeping requirements
- Class 2 devices pose more risk to consumers than do Class 1 devices. Therefore, Class 2 devices are subject to special controls in addition to general controls. Special controls include:
  - Labeling requirements (information that must be included on a product label)
  - Device specific mandatory performance standards
  - Device specific testing requirements
  - Class 2 devices are also subject to general controls.
- Class 3 devices usually support or sustain life, are implanted in the body, or have the potential for unreasonable risk of illness or injury. Examples include pacemakers, breast implants, and HIV diagnostic tests. As a result, Class 3 devices require premarket approval. To receive this, a manufacturer must prove that a device is safe and effective. Class 3 devices are also subject to general controls.

Health Care Service:
Medical or behavioral services including pharmaceuticals, devices, technologies, tests, treatments, therapies, supplies, procedures, hospitalizations, or *provider* visits.

Investigative:
As determined by the Plan, a drug, device or medical treatment or procedure is investigative if reliable evidence does not permit conclusions concerning its safety, effectiveness, or effect on health outcomes

Medical Literature:
Articles from major peer reviewed medical journals that have recognized the drug or combination of drugs' safety and effectiveness for treatment of the indication for which it has be prescribed. Each article shall meet the uniform requirements for manuscripts submitted to biomedical journals established by the International Committee of Medical Journal Editors, or be published in a journal specified by the United States Secretary of Health and Human Services pursuant to United States Code, title 42, section 1395x, paragraph (t), clause (2), item (B), as amended, as acceptable peer review medical literature. Each article must use generally acceptable scientific standards and must not use case reports to satisfy this criterion.

Network meta-analysis:
In the context of a systematic review, is a meta-analysis in which multiple treatments (that is, three or more) are being compared using both direct comparisons of interventions within randomized controlled trials and indirect comparisons across trials based on a common comparator.

Premarket Approval (PMA)

PMA refers to the scientific and regulatory review necessary to evaluate:

- the safety and effectiveness of Class III devices or
- devices that were found not substantially equivalent to a Class I or II predicate through the 510(k) process.

PMA is the most involved process. To reasonably determine that a device is safe and effective. PMA requires:

- scientific evidence that the possible benefits to health from the intended use of a device outweigh the possible risks
- that the device will significantly help a large portion of the target population.

Independence is an important concept for PMAs, meaning that each PMA should establish the safety and effectiveness of the device under review, and that data about one device cannot be used to support another.

Examples of PMAs include digital mammography, minimally invasive and non-invasive glucose testing devices, implanted defibrillators, and implantable middle ear devices.

Priority Review:

The FDA aims to take action on an application within six months, compared to 10 months under standard review. A Priority Review designation directs attention and resources to evaluate drugs that would significantly improve the treatment, diagnosis, or prevention of serious conditions.

Randomized controlled trials:

Prospective studies that measure the effectiveness of a new intervention or treatment. Although no study is likely on its own to prove causality, randomization reduces bias and provides a rigorous tool to examine cause-effect relationships between an intervention and outcome. This is because the act of randomization balances participant characteristics (both observed and unobserved) between the groups allowing attribution of any differences in outcome to the study intervention. This is not possible with any other study design.

Reliable Evidence:

The Plan considers the following categories of reliable evidence, none of which shall be determinative by itself:

1. Whether there is a final approval from the appropriate government regulatory agency, if required. This includes whether a drug or device can be lawfully marketed for its proposed use by the FDA; or if the drug, device or medical treatment or procedure is under study or if further studies are needed to determine its maximum tolerated dose, toxicity, safety or efficacy as compared to standard means of treatment or diagnosis; and
2. Whether there are consensus opinions or recommendations in relevant scientific and medical literature, peer-reviewed journals, or reports of clinical trial committees and other technology assessment bodies. This includes consideration of whether a drug is included in any authoritative compendia as identified by the Medicare program such as, the National Comprehensive Cancer Network Drugs and Biologics Compendium, as appropriate for its proposed use; and
3. Whether there are consensus opinions of national and local health care *providers* in the applicable specialty as determined by a sampling of *providers*, including whether there are protocols used by the treating facility or another facility, studying the same drug, device, medical treatment or procedure.

Substantial Equivalence:
A device is considered substantially equivalent if it has the same intended use and the same technological characteristics as a legally marketed device. A legally marketed device was:

- legally marketed prior to May 28, 1976 ("preamendments device"), for which a PMA is not required, or
- reclassified from Class III to Class II or Class I, or
- found substantially equivalent through the 510(k) process.

Applicants must compare their device to one or more similar legally marketed devices and make and support their substantially equivalent claims. If the device is substantially equivalent to an approved medical device, it is placed in the same class. If it is not substantially equivalent, it becomes non-SE and is placed into Class III.

Examples of 510(k)s include x-ray machines, dialysis machines, fetal monitors, lithotripsy machines, and muscle stimulators.

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines MP/C009
3. Clinical Policy: Investigative Services MP/I001
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DOCUMENT HISTORY:

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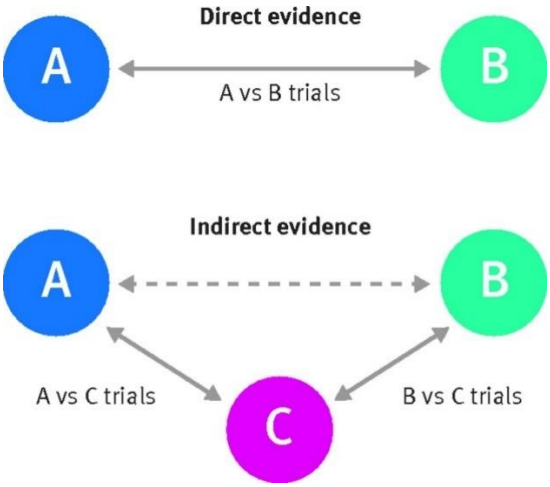
Revised Date: 02/14/20, 08/17/21, 04/28/22

Attachment A

Network meta-analyses incorporates indirect evidence as depicted in C, below



Traditional meta-analyses are A vs. B (drug vs. placebo). They are helpful/necessary for initial drug approval, however, they don't resolve questions about how drugs compare to each other

Network meta-analyses consider how active interventions compare to each other.
In the bottom half of the figure above, A and C were directly compared, and B and C were directly compared, where C = placebo. The question is how A and B compare to each other

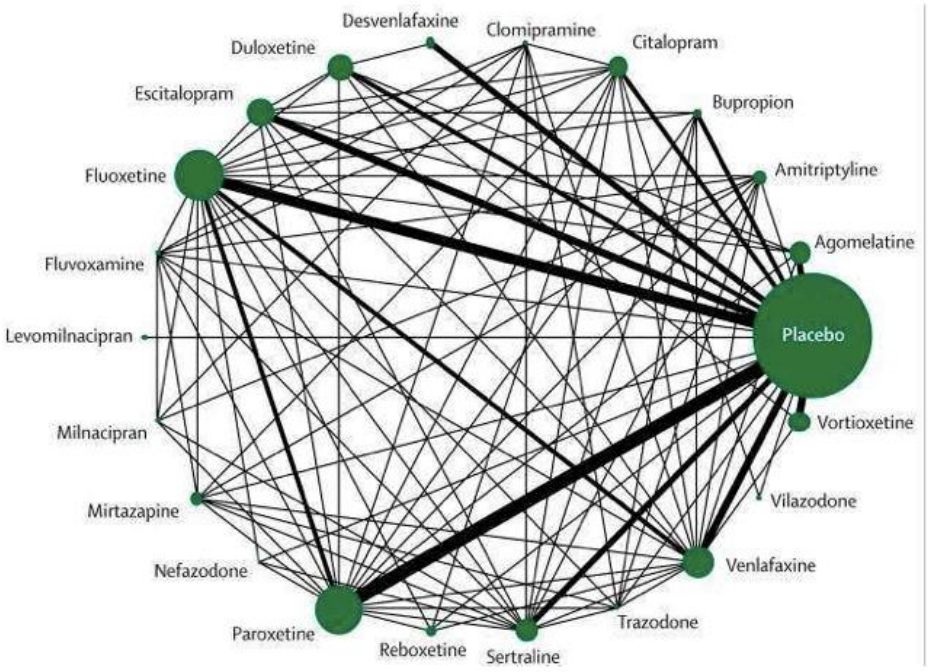
Attachment A (continued)

Example of a meta-analysis regarding antidepressants

WHAT ARE THE FINDINGS?

Between 1979 and 2016, 522 (421 published clinical trials, 86 unpublished trials, and 15 personal communications) double-blind RCTs were included in this meta-analysis. In total, 116,477 patients were included. Patients had a mean age of 44, and 62.3% were female.

Efficacy



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Attachment B

NCCN Categories of Evidence and Consensus

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

All recommendations are category 2A unless otherwise indicated.

Attachment C

Hayes Rating

- A - Established benefit. Published evidence shows conclusively that safety and impact on health outcomes are comparable to or better than standard treatment/testing. Long-term safety and impact on health outcomes have been established, and other important questions concerning application of the technology have been answered.

- B - Some proven benefit. Published evidence indicates that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, there are outstanding questions regarding long-term safety and impact on health outcomes, clinical indications, contraindications, optimal treatment/testing parameters, and/or effects in different patient subpopulations.

- C - Potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.

- D1 - No proven benefit and/or not safe. Published evidence shows that the technology does not improve health outcomes or patient management for the reviewed application(s) or is unsafe.

- D2 - Insufficient evidence. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

NOTE: Reports published before August 2011 may contain a D Rating, which represents a combined D1/D2 Rating. In these reports, there is accompanying text that clarifies whether the D Rating is based on evidence of lack of benefit and/or safety issues, or whether there is insufficient evidence to assess either benefit or safety.

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Attachment D

USPSTF Grade Definitions After July 2012

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

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Attachment E

DynaMed Levels of Evidence

1 Level 1 (likely reliable) Evidence

Representing research results addressing clinical outcomes and meeting an extensive set of quality criteria which minimizes bias.

There are two types of conclusions which can earn a Level 1 label: levels of evidence for conclusions derived from individual studies; and
levels of evidence for conclusions regarding a body of evidence.

2 Level 2 (mid-level) Evidence

Representing research results addressing clinical outcomes and using some method of scientific investigation, but not meeting the quality criteria to achieve Level 1 evidence labeling.

3 Level 3 (lacking direct) Evidence

Representing reports that are not based on scientific analysis of clinical outcomes. Examples include case series, case reports, expert opinion, and conclusions extrapolated indirectly from scientific studies.

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 اعلى رقم الهاتف1-800-332-6501(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 zurVerfügung. 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_ध 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 numer1-800-332-6501 (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 al1-800-332-6501 (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 Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).