

## **Fulvestrant:** **Faslodex®; Fulvestrant Ψ** **(Intramuscular)**

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### **I. Length of Authorization**

Coverage will be provided for 6 months and may be renewed.

### **II. Dosing Limits**

#### **A. Quantity Limit (max daily dose) [NDC Unit]:**

- 250 mg/5 mL single-dose prefilled syringe: 6 syringes first 29 days initially (loading doses), then 2 syringes per 28 days thereafter as maintenance

#### **B. Max Units (per dose and over time) [HCPCS Unit]:**

##### **Ovarian Cancer**

###### **Loading Dosing:**

- 20 billable units on day 1 and 10 billable units on days 15 and 29

###### **Maintenance Dosing:**

- 10 billable units every 28 days

##### **Endometrial Cancer**

- 10 billable units every 28 days

##### **Breast Cancer/Uterine Sarcoma**

###### **Loading Dosing:**

- 20 billable units every 14 days for 3 doses

###### **Maintenance Dosing:**

- 20 billable units every 28 days

### **III. Initial Approval Criteria <sup>1-3</sup>**

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

**Breast Cancer † <sup>1-3,4,7,10-13</sup>**

- Patient is postmenopausal, premenopausal with ovarian ablation/suppression, or male with suppression of testicular steroidogenesis; **AND**
  - Patient has advanced, metastatic, or recurrent unresectable invasive disease; **AND**
    - Patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease with no visceral crisis; **AND**
      - Used as initial therapy; **AND**
        - Used as a single agent ‡; **OR**
        - Used in combination with a CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) ‡; **OR**
        - Used in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole) ‡; **OR**
      - Used as subsequent therapy in patients; **AND**
        - Used as a single agent ‡; **OR**
        - Used in combination with a CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) if a CDK 4/6 inhibitor was not previously used ‡; **OR**
        - Used in combination with everolimus ‡; **OR**
        - Used in combination with alpelisib in patients who have PIK3CA activating mutation positive disease ‡; **OR**
    - Patient has HR-positive, HER2-positive disease ‡; **AND**
      - Used as a single agent or in combination with trastuzumab; **OR**
  - Patient has recurrent unresectable or metastatic inflammatory disease ‡; **AND**
    - Patient has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease with no visceral crisis; **AND**
      - Used as initial therapy; **AND**
        - Used as a single agent; **OR**
        - Used in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole); **OR**
        - Used in combination with a CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) if disease progression on adjuvant endocrine therapy (ET) or with early disease relapse within 12 months of adjuvant ET completion; **OR**
      - Used as subsequent therapy; **AND**
        - Used as a single agent; **OR**
        - Used in combination with a non-steroidal aromatase inhibitor (i.e., anastrozole or letrozole); **OR**
        - Used in combination with everolimus; **OR**
        - Used in combination with a CDK 4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) if a CDK 4/6 inhibitor was not previously used; **OR**

- Used in combination with alpelisib in patients who have PIK3CA activating mutation positive disease; **OR**
- Patient has HR-positive, HER2-positive disease; **AND**
  - Used as a single agent or in combination with trastuzumab

#### **Ovarian Cancer (Epithelial, Fallopian Tube, or Primary Peritoneal Cancer) ‡ 4,9,14**

- Used as single agent therapy; **AND**
- Patient has recurrent low-grade serous carcinoma; **AND**
- Patient has previously received treatment with an aromatase inhibitor (i.e., letrozole, anastrozole, exemestane)

#### **Endometrial Adenocarcinoma (Uterine Neoplasms) ‡ 4,8,15**

- Used as single agent therapy; **AND**
- Patient has grade 1 or 2 endometrioid histology; **AND**
- Used in patients with a small tumor volume or an indolent growth pace; **AND**
- Used as ONE of the following:
  - Adjuvant treatment for stage IV disease; **OR**
  - Treatment for disseminated metastases or locoregional recurrence; **OR**
  - Primary treatment in patients undergoing sequential EBRT for locoregional extrauterine disease that is not suitable for primary surgery; **OR**
  - Primary treatment in patients with distant metastatic disease

#### **Uterine Sarcoma (Uterine Neoplasms) ‡ 4,15**

- Used as single agent therapy; **AND**
- Used in patients with a small tumor volume or an indolent growth pace; **AND**
- Used for low-grade endometrial stromal sarcoma (ESS), adenosarcoma without sarcomatous overgrowth, or ER/PR positive uterine sarcoma; **AND**
  - Used following total hysterectomy for stage II-IV disease; **OR**
  - Used for metastatic or recurrent disease; **OR**
  - Used for disease that is not suitable for primary surgery

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

## **IV. Renewal Criteria <sup>1-3</sup>**

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: bleeding abnormalities, severe injection site reactions (including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy), etc.

## V. Dosage/Administration <sup>1-3,8,9</sup>

Indication	Dose
Breast Cancer & Uterine Sarcoma	<b>Loading Dose:</b> <ul style="list-style-type: none"> <li>• Administer 500 mg intramuscularly (IM) on Days 1, 15, 29</li> </ul> <b>Maintenance Dose:</b> <ul style="list-style-type: none"> <li>• Administer 500 mg IM every 28 days until disease progression or unacceptable toxicity</li> </ul>
Ovarian Cancer	<b>Loading Dose:</b> <ul style="list-style-type: none"> <li>• Administer 500 mg intramuscularly (IM) on Day 1 and 250 mg IM on Days 15 and 29</li> </ul> <b>Maintenance Dose:</b> <ul style="list-style-type: none"> <li>• Administer 250 mg IM every 28 days until disease progression or unacceptable toxicity</li> </ul>
Endometrial Cancer	Administer 250 mg by IM injection every 4 weeks for at least 8 weeks until disease progression or unacceptable toxicity.

## VI. Billing Code/Availability Information

### HCPCS Code:

- J9395 – Injection, fulvestrant, 25 mg; 1 billable unit = 25 mg
- J9393 – Injection, fulvestrant (teva) not therapeutically equivalent to J9395, 25 mg; 1 billable unit = 25 mg
- J9394 – Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg; 1 billable unit = 25 mg

### NDC:

- Faslodex\* 250 mg/5 mL single-dose prefilled syringe: 00310-0720-xx
- Fulvestrant 250 mg/5 mL single-dose prefilled syringe (Teva): 00591-5019-xx
- Fulvestrant 250 mg/5 mL single-dose prefilled syringe (Fresenius Kabi): 63323-0715-xx

– *\* Available as a multi-sourced generic.*

– *Ψ Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a*

*complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book:*

[Approved Drug Products with Therapeutic Equivalence Evaluations / Orange Book / FDA](#)

## VII. References

1. Faslodex [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; January 2021. Accessed February 2023.
2. Fulvestrant [package insert]. North Wales, PA; Teva Pharmaceuticals USA; November 2021. Accessed February 2023.
3. Fulvestrant [package insert]. Lake Zurich, IL; Fresenius Kabi; September 2021. Accessed February 2023.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for fulvestrant. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2023.
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11. Robertson JF, Osborne CK, Howell A, et al. Fulvestrant versus anastrozole for the treatment of advanced breast carcinoma in postmenopausal women: a prospective combined analysis of two multicenter trials. *Cancer*. 2003;98(2):229-238. doi:10.1002/cncr.11468.

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14. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 1.2023. National Comprehensive Cancer Network, 2023. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed February 2023.
15. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Uterine Neoplasms Version 1.2023. National Comprehensive Cancer Network, 2022. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed February 2023.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast



ICD-10	ICD-10 Description
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast

ICD-10	ICD-10 Description
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary



## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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- Written information in other formats (large print, audio, accessible electronic formats, other formats)

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PreferredOne Community Health Plan  
PO Box 59052  
Minneapolis, MN 55459-0052  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

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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>.

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XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

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PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

## PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:

Provides free aids and services to people with disabilities 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 services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC 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:

Grievance Specialist  
PreferredOne Insurance Company  
PO Box 59212  
Minneapolis, MN 55459-0212  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist 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>.

## Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013)។

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013)፡፡

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လို့လိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).