Prolia (denosumab)
Injection, for subcutaneous use

Policy Number: MC/PC 032
Effective Date: September 1, 2024

Instructions for Use

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Related Policies

- N/A

Coverage Rationale

Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture

For initial coverage of Prolia (denosumab) Injection for the treatment of postmenopausal women with osteoporosis or osteopenia at a high risk for fracture, the following will be required:

- Diagnosis of postmenopausal osteoporosis or osteopenia **and**
- One of the following:
  - Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) **or**
  - Both of the following:
    - BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) **and**
    - One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:
      - Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
      - Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions **or**
  - History of one of the following resulting from minimal trauma:
    - Vertebral compression fracture
    - Fracture of the hip
    - Fracture of the distal radius
    - Fracture of the pelvis
    - Fracture of the proximal humerus **and**
- Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g. alendronate)

For reauthorization coverage of Prolia (denosumab) Injection for the treatment of postmenopausal women with osteoporosis or osteopenia at a high risk for fracture, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effect.

Increase bone mass in men at high risk for fracture

For initial coverage of Prolia (denosumab) Injection for the treatment of increase bone mass in men at high risk for fracture, the following will be required:

- Patient is a male with osteoporosis or osteopenia **and**
- One of the following:
    - Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) **or**
    - Both of the following:
        - BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) **and**
        - One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:
            - Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
            - Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions **or**
    - History of one of the following resulting from minimal trauma:
        - Vertebral compression fracture
        - Fracture of the hip
        - Fracture of the distal radius
        - Fracture of the pelvis
        - Fracture of the proximal humerus **and**
- Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

For reauthorization coverage of Prolia (denosumab) Injection for the treatment of increase bone mass in men at high risk for fracture is provided, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer

For initial coverage of Prolia (denosumab) Injection for the treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer, the following will be required:

- Diagnosis of nonmetastatic prostate cancer **and**
- Patient is undergoing androgen deprivation therapy with one of the following:
    - Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)] **or**
    - Bilateral orchiectomy (i.e., surgical castration) **and**
- One of the following:
    - Age greater than or equal to 70 years **or**
    - Both of the following:
        - Age less than 70 years **and**
        - One of the following:

- Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) **or**
- History of one of the following resulting from minimal trauma:
    - Vertebral compression fracture
    - Fracture of the hip
    - Fracture of the distal radius
    - Fracture of the pelvis
    - Fracture of the proximal humerus **and**
- Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., zoledronic acid)

For reauthorization coverage of Prolia (denosumab) Injection for the treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer, the following will be required:

- Patient is undergoing androgen deprivation therapy with one of the following:
    - Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)] **or**
    - Bilateral orchiectomy (i.e., surgical castration) **and**
- No evidence of metastases **and**
- Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer

For initial coverage of Prolia (denosumab) Injection for the treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer, the following will be required:

- Diagnosis of breast cancer **and**
- Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) **and**
- One of the following:
    - Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) **or**
    - History of one of the following resulting from minimal trauma:
        - Vertebral compression fracture
        - Fracture of the hip
        - Fracture of the distal radius
        - Fracture of the pelvis
        - Fracture of the proximal humerus **and**
- Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

For reauthorization coverage of Prolia (denosumab) Injection for the treatment of Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer, the following will be required:

- Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) **and**
- Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

Glucocorticoid-induced osteoporosis at high risk for fracture

For initial coverage of Prolia (denosumab) Injection for treatment of glucocorticoid-induced osteoporosis at high risk for fracture, the following will be required:

- Diagnosis of glucocorticoid-induced osteoporosis **and**

- Patient is initiating or continuing on greater than or equal to 7.5 mg/day of prednisone (or its equivalent) and is expected to remain on glucocorticoid therapy for at least 6 months **and**
- One of the following:
    - BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site) **or**
    - One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:
        - Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
        - Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions **or**
    - History of one of the following fractures resulting from minimal trauma:
        - Vertebral compression fracture
        - Fracture of the hip
        - Fracture of the distal radius
        - Fracture of the pelvis
        - Fracture of the proximal humerus **or**
    - One of the following:
        - Glucocorticoid dosing of at least 30 mg per day
        - Cumulative glucocorticoid dosing of at least 5 grams per year **and**
- Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate)

For reauthorization coverage of Prolia (denosumab) Injection for the treatment of glucocorticoid-induced osteoporosis at high risk for fracture, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J0897	Injection, denosumab, 1 mg

ICD-10 Code	Description
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
C50.111	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
C50.211	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

ICD-10 Code	Description
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
C50.411	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
C50.511	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
C50.611	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
C50.811	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
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C61	Malignant neoplasm of prostate
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
M80.00XA - M80.88XS	Age-related osteoporosis with current pathological fracture, unspecified site, initial encounter for fracture - Other osteoporosis with current pathological fracture, vertebra(e), sequela
M80.8AXA	Other osteoporosis with current pathological fracture, other site, initial encounter for fracture
M80.8AXD	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing
M80.8AXG	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing
M80.8AXK	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion

ICD-10 Code	Description
M80.8AXP	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion
M80.8AXS	Other osteoporosis with current pathological fracture, other site, sequela
M81.0	Age-related osteoporosis without current pathological fracture
M81.8	Other osteoporosis without current pathological fracture
M85.9	Disorder of bone density and structure, unspecified
M89.9	Disorder of bone, unspecified
Z79.52	Long term current use of systemic steroids
Z79.811	Long term [current] use of aromatase inhibitors
Z79.818	Long term (current) use of other agents affecting estrogen receptors and estrogen levels
Z85.3	Personal history of malignant neoplasm of breast
Z86.000	Personal history of in-situ neoplasm of breast
Z87.310	Personal history of healed osteoporosis fracture

Background

Osteoporosis is the most common bone disease and is characterized by low bone mass and microarchitectural deterioration of bone tissue, leading to bone fragility and consequent susceptibility to fracture (LeBoff et al 2022). The Bone Health and Osteoporosis Foundation estimates that 10.2 million people in the United States have osteoporosis and 43.4 million have low bone mass. More than 2 million osteoporosis-related fractures occur annually, with more than 70% of these occurring in women. Age is an important risk factor for bone loss. By age 60, half of white women have osteopenia or osteoporosis (Camacho et al 2020). According to the World Health Organization (WHO), osteoporosis is defined by a bone mineral density (BMD) at the hip or spine that is less than or equal to 2.5 standard deviations below the expected average for a healthy young person. Utilizing a reference population of young healthy individuals is common when measuring BMD and is known as a T-score (WHO 2007). Fractures are the most clinically significant physical manifestation of postmenopausal osteoporosis, and low bone mass is the primary indicator of fracture risk (Camacho et al 2020).

Common agents used to treat osteoporosis include calcitonin (Miacalcin), an estrogen agonist/antagonist (Evista [raloxifene]), the parathyroid hormone analogs (Forteo [teriparatide], Teriparatide [teriparatide], and Tymlos [abaloparatide]), the receptor activator of nuclear factor-kappa B ligand (RANKL) inhibitor (Prolia [denosumab]), and the sclerostin inhibitor (Evenity [romosozumab]). Denosumab binds to RANKL, a transmembrane of soluble protein essential for the formation, function, and survival of osteoclasts, the cells responsible for bone resorption. Denosumab prevents RANKL from activating its receptor, RANK, on the surface of osteoclasts and their precursors. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone.

These agents also have other indications including: reduction in the risk of invasive breast cancer in postmenopausal women with osteoporosis; reduction in the risk of invasive breast cancer in postmenopausal women at high risk of invasive breast cancer; increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; treatment of Paget's disease; treatment of hypercalcemia; treatment of glucocorticoid-induced osteoporosis at high risk of fracture; treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer; and treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

Clinical Evidence

Osteoporosis
Of the available clinical trial data evaluating the safety and efficacy of denosumab in postmenopausal women with osteoporosis who are at high risk of fracture, only 1 placebo-controlled trial (the FREEDOM trial) demonstrated a reduction in the risk of fracture with denosumab. In this trial, after 36 months, there were significant reductions with denosumab compared to placebo in the incidence of new vertebral, nonvertebral and hip fractures. (Cummings et al 2009). A 3-year extension trial maintained patients randomized to denosumab on active treatment for a total of 6 years and crossed over the placebo patients to denosumab treatment for a total of 3 years. For patients on denosumab for 6 years, BTMs were maintained at lower than pretreatment levels and BMD continued to increase. Fracture incidence in the long-term group remained low and below the rates reported in the FREEDOM placebo group. (Bone et al 2013). A 7-year extension of FREEDOM, for a total of 7 to 10 years of exposure to denosumab, further confirmed a low fracture incidence rate with low rates of AEs (Bone et al 2017). Additionally, BMD at the lumbar spine, total hip, femoral neck, and radius continued to increase, suggesting no plateau to BMD benefits with denosumab.

Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
When compared to placebo, denosumab significantly prolonged bone-metastasis-free survival (composite of time to first occurrence of bone metastasis and death from any cause) in men with non-metastatic prostate cancer (treatment difference, 4.2 months; HR, 0.85; 95% CI, 0.73 to 0.98; p = 0.028). There was no difference in overall survival observed between the 2 treatment groups. In this trial, BMD evaluations were not performed; however, it was noted that biochemical markers of bone turnover significantly decreased with denosumab compared to placebo (p < 0.001 for all). Of note, the FDA-approved dosing was not evaluated in this trial; denosumab was administered once monthly (Smith et al 2012). The ADAMO trial showed that denosumab therapy administered every 6 months continued to increase BMD in men with low BMD throughout the second year of treatment (Langdahl et al 2015).

Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
The safety and efficacy of denosumab for the treatment of bone loss in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer were established in a 2 year, double-blind, placebo-controlled, randomized trial enrolling 252 women (Ellis et al 2008). Patients were randomized to subcutaneous denosumab every 6 months (n = 127) or placebo (n = 125) for a total of 4 doses; all patients received supplemental calcium and vitamin D. Overall, denosumab increased BMD at the lumbar spine at 12 and 24 months by 5.5% and 7.6%, respectively, compared to placebo (p < 0.0001 at both time points). Furthermore, after 2 years, denosumab increased BMD at the lumbar spine (-1.4% placebo, +4.8% denosumab), total hip (-1.0% placebo, +3.8% denosumab), and femoral neck (-0.8% placebo, +2.8% denosumab). In a double-blind, placebo-controlled, Phase 3 trial evaluated denosumab vs placebo in 3420 postmenopausal women with early hormone-receptor positive breast cancer receiving treatment with aromatase inhibitors the primary outcome measure of time to first fracture was significantly delayed in the denosumab group compared to placebo (hazard ratio [HR], 0.50; 95% CI, 0.39 to 0.65; p < 0.0001). The incidence of AEs was similar in both treatment groups. (Gnant et al 2015).

Treatment of Glucocorticoid-Induced Osteoporosis
A systematic review and meta-analysis assessed the effect of denosumab vs bisphosphonate treatment on BMD, fractures and safety in patients with glucocorticoid-induced osteoporosis. Collective data from 3 clinical trials demonstrated that 1 year of denosumab therapy increased lumbar (2.32%, 95% CI, 1.73% to 2.91%, p < 0.0001) and hip (1.52%, 95% CI, 1.1% to 1.94%, p < 0.0001) BMD more than bisphosphonates. The analysis found similar rates of fracture incidence, AEs, and infection between both treatments (Yanbeiy and Hansen 2019). The impact of denosumab compared to risedronate on BMD was evaluated in 795 patients with glucocorticoid-induced osteoporosis. At 24 months, the increase in lumbar spine and total hip BMD was significantly higher with denosumab compared to risedronate in patients on glucocorticoids for less than 3 months as well as for those taking glucocorticoids for greater than 3 months. The incidence of discontinuation of treatment due to AEs was 7.9% with denosumab and 9.6% with risedronate and the incidence of infection was approximately 36% in both groups (Saag et al 2019).

Clinical Guidelines

To prevent and/or treat osteoporosis in postmenopausal women and men, national guidelines recommend adequate calcium and vitamin D intake, weight bearing exercise, cessation of smoking, and limiting alcohol intake (American College of Gynecology and Obstetricians [ACOG] 2022, North American Menopause Society 2021, Adler et al 2016, Buckley et al 2017, Camacho et al 2020, Conley et al 2020, Eastell et al 2019, LeBoff et al 2022, Qaseem et al 2023, Watts et al 2012). Within the various osteoporosis treatment guidelines (including postmenopausal osteoporosis, glucocorticoid-induced osteoporosis, and osteoporosis in men), there is general agreement that treatment is indicated for patients > 50 years of age who have experienced a hip or vertebral fracture or have a bone density T-score ≤ -2.5 (ACOG 2022, North American Menopause Society 2021, Adler et al 2016, Buckley et al 2017, Camacho et al 2020, Eastell et al 2019, LeBoff et al 2022, Qaseem et al 2023, Watts et al 2012). For most patients with osteoporosis, the majority of guidelines recommend initial or first-line treatment with an oral bisphosphonate (i.e., alendronate or risedronate) to reduce fracture risk. For patients who are unable to tolerate oral bisphosphonates or who are nonadherent, an intravenous agent (zoledronic acid or denosumab) is generally recommended (ACOG 2022, North American Menopause Society 2021, Buckley et al 2017, Camacho et al 2020, Conley et al 2020, Eastell et al 2019, LeBoff et al 2022, Shoback et al 2020, Qaseem et al 2023, Watts et al 2012). Alendronate, risedronate, zoledronic acid, and denosumab have evidence for "broad spectrum" antifracture efficacy (i.e., spine, hip, and nonvertebral fracture risk reduction) (Camacho et al 2020; Qaseem et al 2023).

For patients with osteoporosis at high risk of fracture, treatment with denosumab, zoledronic acid, and the injectable anabolic agents (abaloparatide, romosozumab, and teriparatide) are generally recommended as follows:

- The 2022 ACOG guidelines for postmenopausal osteoporosis recommend bisphosphonates or denosumab as initial therapy for patients at high-fracture risk. Denosumab is recommended for those who prefer every 6-month subcutaneous administration.
- The 2020 American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) guidelines for postmenopausal osteoporosis recommend initial therapy with abaloparatide, denosumab, romosozumab, teriparatide, or zoledronic acid in patients at very high fracture risk (e.g. older women who have had multiple vertebral fractures or hip fractures or have very low T-scores) or in those who may not be candidates for oral bisphosphonates (Camacho et al 2020).

Patients with breast or prostate cancer receiving adjuvant aromatase inhibitor therapy or androgen deprivation therapy (ADT), respectively, may require treatment with osteoporosis agents (i.e., bisphosphonates or denosumab) as supportive therapy to maintain or to improve BMD (National Comprehensive Cancer Network [NCCN] 2023a, NCCN 2023b).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Prolia is a RANK ligand (RANKL) inhibitor indicated for treatment:

- of postmenopausal women with osteoporosis at high risk for fracture
- to increase bone mass in men with osteoporosis at high risk for fracture
- of glucocorticoid-induced osteoporosis in men and women at high risk for fracture
- to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer
- to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer

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Policy History/Revision Information

Date	Summary of Changes
10/18/2023	Approved by OptumRx P&T Committee
08/15/2024	Annual Review. Updated reauth language to standard verbiage of "Patient demonstrates positive clinical response to therapy". Updated references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Archived Policy Versions (Internal Only)

Effective Date	Policy Number	Policy Title
mm/dd/yyyy – mm/dd/yyyy	######	Title of Policy Hyperlinked to KL or Other Internal Location

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).

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