

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Ilaris Prior Authorization Policy

• Ilaris® (canakinumab for subcutaneous injection – Novartis)

REVIEW DATE: 05/26/2021

OVERVIEW

Ilaris, an interleukin- 1β (IL- 1β) blocker, is indicated for the following autoinflammatory periodic fever syndromes:¹

- **Cryopyrin-Associated Periodic Syndromes** (CAPS), including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome, for treatment of patients who are ≥ 4 years of age.
- Familial Mediterranean fever, in adult and pediatric patients.
- Hyperimmunoglobulin D syndrome/mevalonate kinase deficiency, in adult and pediatric patients.
- Still's disease, including Active adult-onset Still's disease and systemic juvenile idiopathic arthritis (SJIA), in patients ≥ 2 years of age.
- Tumor necrosis factor receptor associated periodic syndrome (TRAPS), in adult and pediatric patients.

In the pivotal study for period fevers, patients were required to be at least 2 years of age with a disease flare, defined as a C-reactive protein level ≥ 10 mg/L. Prior to starting Ilaris, a minimum level of disease activity at baseline was required for familial Mediterranean fever (at least one flare per month despite colchicine), hyperimmunoglobulin D syndrome/mevalonate kinase deficiency (\geq three febrile acute flares within the previous 6 month period), and TRAPs (\geq six flares per year). In this study, patients were assessed for a response following 4 months of treatment with Ilaris.

Guidelines

Ilaris is used for a variety of periodic fever syndromes and inflammatory conditions.

- **CAPS:** A consensus protocol for hereditary autoinflammatory syndromes (2020) lists Ilaris as a treatment option across the spectrum of CAPS.¹¹ Continuous therapy is recommended for severe, continuous disease. For those who do not achieve remission or minimal disease activity following 1 to 3 months of treatment, dose escalation or shortened dosing interval is among the treatment options. On-demand therapy is also a treatment option for those patients who have intermittent, mild disease with low disease activity.
- Familial Mediterranean Fever: Guidelines for familial Mediterranean fever from the European League Against Rheumatism (EULAR) [2016] note that treatment goals are to prevent the clinical attacks and to suppress chronic subclinical inflammation.⁶ IL-1 blockade is an option for patients with protracted febrile myalgia. In patients who develop amyloidosis, the maximal tolerated dose of colchicine and biologics (especially IL-1 blockade) are recommended.
- **Mevalonate Kinase Deficiency:** European guidelines for autoinflammatory disorders (2015) recommend consideration of short-term use of IL-1 blockers for termination of attacks and to limit or prevent steroid adverse events.⁵ Maintenance therapy with an IL-1 blocker may be used in patients with mevalonate kinase deficiency and frequent attacks and/or subclinical inflammation between attacks. A consensus protocol for hereditary autoinflammatory syndromes (2020) lists Ilaris as a treatment option across the spectrum of mevalonate kinase deficiency/hyperimmunoglobulin D syndrome.¹¹ Continuous therapy is recommended for severe,



continuous disease. For those who do not achieve remission or minimal disease activity following 1 to 3 months of treatment, dose escalation or shortened dosing interval is among the treatment options. On-demand therapy is also a treatment option for those patients who have intermittent, mild disease.

- **SJIA:** There are standardized treatment plans published for use of Ilaris.^{7,8} At Month 3, patients with unchanged or worsening disease or patients whose steroid dose is > 50% of the starting dose should have an increase in prednisone plus either addition of methotrexate or change to Actemra. Guidelines from the American College of Rheumatology for the management of SJIA (2013) mention Ilaris as a treatment alternative, depending upon the manifestations of SJIA being treated. While there are a number of other effective options for treating synovitis in patients with active SJIA, effective options for treatment of macrophage activation syndrome are much more limited and include Kineret (anakinra subcutaneous injection), calcineurin inhibitors, and systemic corticosteroids (no preferential sequencing noted). Although use of Ilaris is uncertain in some situations, macrophage activation syndrome is a potentially life-threatening situation with limited treatment options.
- TRAPS: European guidelines for autoinflammatory disorders (2015) note that IL-1 blockade is beneficial for the majority of patients; maintenance with IL-1 blockade, which may limit corticosteroid exposure, may be used in patients with frequent attacks and/or subclinical inflammation between attacks. A consensus protocol for hereditary autoinflammatory syndromes (2020) lists Ilaris as a treatment option across the spectrum of TRAPS. Continuous therapy is recommended for severe, continuous disease. For those who do not achieve remission or minimal disease activity following 1 to 3 months of treatment, dose escalation or shortened dosing interval is among the treatment options. On-demand therapy is also a treatment option for those patients who have intermittent, mild disease.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Ilaris. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Ilaris as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ilaris to be prescribed by or in consultation with a physician who specializes in the condition being treated.

All reviews for use of Ilaris for COVID-19 and/or cytokine release syndrome associated with COVID-19 will be forwarded to the Medical Director.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ilaris is recommended in those who meet the following criteria:

FDA-Approved Indications

- 1. Cryopyrin-Associated Periodic Syndromes (CAPS) [including Familial Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease {NOMID} or Chronic Infantile Neurological Cutaneous and Articular {CINCA} Syndrome]. Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy. Approve for 3 months if the patient meets the following conditions (i and ii):



- i. Patient is ≥ 4 years of age; AND
- **ii.** Ilaris is prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist.
- **B)** Patient is Currently Receiving Ilaris. Approve for 1 year if the patient has had a response, as determined by the prescriber.
- **2. Familial Mediterranean Fever.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
 - i. Patient is ≥ 2 years of age; AND
 - ii. Patient has tried colchicine, unless contraindicated; AND
 - **iii.** Patient will be taking Ilaris in combination with colchicine, unless colchicine is contraindicated or not tolerated; AND
 - iv. Prior to starting Ilaris, the patient meets both of the following (a and b):
 - a) C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; AND
 - **b)** Patient has a history of at least one flare per month despite use of colchicine, OR was hospitalized for a severe flare; AND
 - v. The medication is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, gastroenterologist, oncologist, or hematologist.
 - **B)** Patient is Currently Receiving Ilaris. Approve for 1 year if the patient has experienced a reduction in the frequency and/or severity of attacks.
- **3. Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient is ≥ 2 years of age; AND
 - ii. Prior to starting Ilaris, the patient meets both of the following (a and b):
 - a) C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; AND
 - b) Patient has a history of at least three febrile acute flares within the previous 6-month period OR was hospitalized for a severe flare; AND
 - **iii.** The medication is prescribed by or in consultation with a rheumatologist, nephrologist, geneticist, oncologist, or hematologist.
 - **B)** Patient is Currently Receiving Ilaris. Approve for 1 year if the patient has experienced a reduction in the frequency and/or severity of attacks.
- **4. Stills Disease, Adult Onset.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - **A)** <u>Initial Therapy</u>. Approve for 3 months (which is adequate for three doses) if the patient meets ALL of the following conditions (i, ii, <u>and</u> iii):
 - i. Patient is ≥ 18 years of age; AND
 Note: If the patient is < 18 years of age, refer to criteria for systemic juvenile idiopathic arthritis.
 - ii. Patient meets ONE of the following conditions (a, b, or c):
 - Patient has tried at least TWO other biologics; OR
 Note: Examples of biologics include Actemra (tocilizumab intravenous infusion, tocilizumab subcutaneous injection), Kineret (anakinra subcutaneous injection), Orencia



(abatacept intravenous infusion, abatacept subcutaneous injection), an etanercept product, adalimumab product, or infliximab product.

- **b)** Patient meets BOTH of the following [(1) and (2)]:
 - (1) Patient has features of poor prognosis, as determined by the prescriber; AND Note: Examples of features of poor prognosis include arthritis of the hip, radiographic damage, 6-month duration of significant active systemic disease, defined by: fever, elevated inflammatory markers, or requirement for treatment with systemic glucocorticoids.
 - (2) Patient has tried Actemra or Kineret; OR
- c) Patient meets BOTH of the following [(1) and (2)]:
 - (1) Patient has active systemic features with concerns of progression to macrophage activation syndrome, as determined by the prescriber; AND
 - (2) Patient has tried Kineret; AND
- iii. Ilaris is prescribed by or in consultation with a rheumatologist.
- **B)** Patient is Currently Receiving Ilaris. Approve for 1 year if the patient has had a response as determined by the prescriber.

<u>Note</u>: Examples of responses to therapy include resolution of fevers or rash, improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue; improved function or activities of daily living, and reduced dosage of corticosteroids. The patient may not have a full response, but there should have been a recent or past response to Ilaris.

- **5. Systemic Juvenile Idiopathic Arthritis (SJIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) <u>Initial Therapy</u>. Approve for 3 months (which is adequate for three doses) if the patient meets ALL of the following conditions (i, ii, and iii):
 - i. Patient is ≥ 2 years of age; AND
 - ii. Patient meets ONE of the following conditions $(a, b, \underline{or} c)$:
 - a) Patient has tried at least TWO other biologics; OR <u>Note</u>: Examples of biologics for SJIA include Actemra (tocilizumab intravenous infusion, tocilizumab subcutaneous injection), Kineret (anakinra subcutaneous injection), Orencia (abatacept intravenous infusion, abatacept subcutaneous injection), an etanercept product, adalimumab product, or infliximab product.
 - **b)** Patient meets BOTH of the following [(1) and (2)]:
 - (1) Patient has features of poor prognosis, as determined by the prescriber; AND Note: Examples of features of poor prognosis include arthritis of the hip, radiographic damage, 6-month duration of significant active systemic disease, defined by: fever, elevated inflammatory markers, or requirement for treatment with systemic glucocorticoids.
 - (2) Patient has tried Actemra or Kineret; OR
 - c) Patient meets BOTH of the following [(1) and (2)]:
 - (1) Patient has features of SJIA with active systemic features with concerns of progression to macrophage activation syndrome, as determined by the prescriber; AND
 - (2) Patient has tried Kineret; AND
 - iii. Ilaris is prescribed by or in consultation with a rheumatologist.
 - **B)** Patient is Currently Receiving Ilaris. Approve for 1 year if the patient has had a response as determined by the prescriber.

<u>Note</u>: Examples of responses to therapy include resolution of fevers or rash, improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue; improved function or activities of daily living, and reduced dosage of corticosteroids. The patient may not have a full response, but there should have been a recent or past response to Ilaris.



- **6. Tumor Necrosis Factor Receptor Associated Periodic Syndrome.** Approve for the duration noted if the patient meets ONE of the following (A <u>or</u> B):
 - A) Initial Therapy. Approve for 4 months if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient is ≥ 2 years of age; AND
 - ii. Prior to starting Ilaris, the patient meets both of the following (a and b):
 - a) C-reactive protein level is ≥ 10 mg/L OR elevated to at least two times the upper limit of normal for the reporting laboratory; AND
 - b) Patient has a history of at least six flares per year OR was hospitalized for a severe flare; AND
 - **iii.** The medication is prescribed by or in consultation with a rheumatologist, geneticist, nephrologist, oncologist, or hematologist.
 - **B)** Patient is Currently Receiving Ilaris. Approve for 1 year if the patient has experienced a reduction in the the frequency and/or severity of attacks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ilaris is not recommended in the following situations:

- 1. Concurrent Biologic Therapy. Ilaris has not been evaluated and should not be administered in combination with another biologic agent for an inflammatory condition (see Appendix for examples). An increased incidence of serious infections has been associated with another IL-1 blocker, Kineret, when given in combination with tumor necrosis factor inhibitor in patients with rheumatoid arthritis. Concomitant administration of Ilaris and other agents that block IL-1 or its receptors is not recommended.
- **2. COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director. Note: This includes requests for cytokine release syndrome associated with COVID-19.
- **3. Rheumatoid Arthritis.** Efficacy is not established. In a 12-week, Phase II, placebo-controlled, double-blind study, 277 patients who had failed methotrexate were randomized to Ilaris or placebo. Although the ACR 50 at Week 12 was higher for Ilaris 150 mg (given every 4 weeks) compared with placebo (26.5% vs. 11.4%, respectively; P = not significant), there was not a statistically significant difference in ACR 50 for the other Ilaris treatment groups (Ilaris 300 mg every 2 weeks; Ilaris 600 mg loading dose followed by 300 mg every 2 weeks).
- **4.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

- 1. Ilaris® for subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2020.
- 2. Shinkai K, McCalmont TH, Leslie KS. Cryopyrin-associated periodic syndromes and autoinflammation. *Clin Exp Dermatol*. 2008:33:1-9.
- 3. Ozen S, Hoffman HM, Frenkel J, et al. Familial Mediterranean Fever (FMF) and beyond: a new horizon. Fourth International Congress on the Systemic Autoinflammatory Diseases held in Bethesda, USA; 6-10 November 2005. *Ann Rheum Dis.* 2006;65(7):961-964.
- 4. Genetics Home Reference. US National Library of Medicine. Available at: https://ghr.nlm.nih.gov/. Accessed on May 3, 2021. Search terms: TRAPS, familial Mediterranean fever, MKD.
- 5. ter Haar NM, Oswald M, Jeyaratnam J, et al. Recommendations for the management of autoinflammatory diseases. *Ann Rheum Dis.* 2015;74(9):1636-1644.



- 6. Ozen S, Demirkaya E, Erer B, et al. EULAR recommendations for the management of familial Mediterranean fever. *Ann Rheum Dis.* 2016;75(4):644-651.
- 7. Kimura Y, Morgan DeWitt E, Beukelman T, et al. Adding Canakinumab to the Childhood Arthritis and Rheumatology Research Alliance Consensus Treatment Plans for Systemic Juvenile Idiopathic Arthritis: comment on the article by DeWitt et al. *Arthritis Care Res (Hoboken)*. 2014;66(9):1430-1431.
- 8. DeWitt EM, Kimura Y, Beukelman T, et al. Consensus treatment plans for new-onset systemic juvenile idiopathic arthritis. *Arthritis Care Res (Hoboken)*. 2012;64(7):1001-1010.
- 9. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum*. 2013;65(10):2499-2512.
- 10. Alten R, Gomez-Reino J, Durez P, et al. Efficacy and safety of the human anti-IL-1β monoclonal antibody canakinumab in rheumatoid arthritis: results of a 12-week, Phase II, dose-finding study. *BMC Musculoskelet Disord.* 2011;12:153.
- 11. Hansmann S, Lainka E, Horneff G, et al. Consensus protocols for the diagnosis and management of the hereditary autoinflammatory syndromes CAPS, TRAPS and MKD/HIDS: a German PRO-KIND initiative. *Pediatr Rheumatol Online J.* 2020;18(1):17.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|-------------------|--|-------------|
| Early annual | Systemic Juvenile Idiopathic Arthritis: For the exceptions applying to patients with | 04/22/2020 |
| revision | a poor prognosis and for those with active systemic features and concerns of progression | |
| | to macrophage activation syndrome, wording was updated to more generally allow this | |
| | determination by the prescriber (criteria previously specified this was according to the | |
| | prescribing physician). | |
| Selected Revision | Systemic Juvenile Idiopathic Arthritis: Resolution of rash was added as an example | 06/24/2020 |
| | of a response to therapy. | |
| | Still's Disease, Adult Onset: Criteria were updated to align with the new labeling. | |
| | Criteria for systemic juvenile idiopathic arthritis also apply to adult-onset Still's disease. | |
| Annual Revision | Familial Mediterranean Fever: To align with the pivotal study design, the following | 05/26/2021 |
| | requirements were added for initial therapy: an age requirement ≥ 2 years of age; a | |
| | previous trial and concomitant use with colchicine, unless contraindicated or not | |
| | tolerated; a minimum requirement for elevation in C-reactive protein level; and a history | |
| | of at least one flare per month despite colchicine, unless the patient was previously | |
| | hospitalized for a severe flare. For a patient who is currently receiving Ilaris, a response | |
| | to therapy was clarified to require a reduction in the frequency and/or severity of attacks; | |
| | previously, a response to therapy was not defined and was determined by the prescriber. | |
| | Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency: To align with | |
| | the pivotal study design, the following requirements were added for initial therapy: an | |
| | age requirement ≥ 2 years of age; a minimum requirement for elevation in C-reactive | |
| | protein level; and a history of at least three flares within the previous 6 months, unless | |
| | the patient was previously hospitalized for a severe flare. For a patient who is currently | |
| | receiving Ilaris, a response to therapy was clarified to require a reduction in the | |
| | frequency and/or severity of attacks; previously, a response to therapy was not defined | |
| | and was determined by the prescriber. | |
| | Tumor Necrosis Factor Receptor Associated Periodic Syndrome: To align with the | |
| | pivotal study design, the following requirements were added for initial therapy: an age | |
| | requirement ≥ 2 years of age; a minimum requirement for elevation in C-reactive protein | |
| | level; and a history of at least six flares per year, unless the patient was previously | |
| | hospitalized for a severe flare. For a patient who is currently receiving Ilaris, a response | |
| | to therapy was clarified to require a reduction in the frequency and/or severity of attacks; | |
| | previously, a response to therapy was not defined and was determined by the prescriber. | |



APPENDIX

| | Mechanism of Action | Examples of Inflammatory Indications* | | |
|---|------------------------------|---------------------------------------|--|--|
| Biologics | | | | |
| Adalimumab SC Products (Humira®, biosimilars) | Inhibition of TNF | AS, CD, JIA, PsO, PsA, RA, UC | | |
| Cimzia® (certolizumab pegol SC injection) | Inhibition of TNF | AS, CD, nr-axSpA, PsO, PsA, RA | | |
| Etanercept SC Products (Enbrel®, biosimilars) | Inhibition of TNF | AS, JIA, PsO, PsA | | |
| Infliximab IV Products (Remicade®, biosimilars) | Inhibition of TNF | AS, CD, PsO, PsA, RA, UC | | |
| Simponi®, Simponi® Aria™ (golimumab SC | Inhibition of TNF | SC formulation: AS, PsA, RA, UC | | |
| injection, golimumab IV infusion) | | IV formulation: AS, PJIA, PsA, RA | | |
| Actemra® (tocilizumab IV infusion, tocilizumab SC | Inhibition of IL-6 | SC formulation: PJIA, RA, SJIA | | |
| injection) | | IV formulation: PJIA, RA, SJIA | | |
| Kevzara® (sarilumab SC injection) | Inhibition of IL-6 | RA | | |
| Orencia® (abatacept IV infusion, abatacept SC | T-cell costimulation | SC formulation: JIA, PSA, RA | | |
| injection) | modulator | IV formulation: JIA, PsA, RA | | |
| Rituximab IV Products (Rituxan®, biosimilars) | CD20-directed cytolytic | RA | | |
| | antibody | | | |
| Kineret® (anakinra SC injection) | Inhibition of IL-1 | JIA^, RA | | |
| Stelara® (ustekinumab SC injection, ustekinumab | Inhibition of IL-12/23 | SC formulation: CD, PsO, PsA, UC | | |
| IV infusion) | | IV formulation: CD, UC | | |
| Siliq [™] (brodalumab SC injection) | Inhibition of IL-17 | PsO | | |
| Cosentyx [™] (secukinumab SC injection) | Inhibition of IL-17A | AS, nr-axSpA, PsO, PsA | | |
| Taltz® (ixekizumab SC injection) | Inhibition of IL-17A | AS, nr-axSpA, PsO, PsA | | |
| Ilumya [™] (tildrakizumab-asmn SC injection) | Inhibition of IL-23 | PsO | | |
| Skyrizi [™] (risankizumab-rzaa SC injection) | Inhibition of IL-23 | PsO | | |
| Tremfya [™] (guselkumab SC injection) | Inhibition of IL-23 | PsO | | |
| Entyvio [™] (vedolizumab IV infusion) | Integrin receptor antagonist | CD, UC | | |
| Targeted Synthetic DMARDs | | | | |
| Otezla® (apremilast tablets) | Inhibition of PDE4 | PsO, PsA | | |
| Olumiant® (baricitinib tablets) | Inhibition of JAK pathways | RA | | |
| Rinvoq® (upadacitinib extended-release tablets) | Inhibition of JAK pathways | RA | | |
| Xeljanz® (tofacitinib tablets) | Inhibition of JAK pathways | RA, PJIA, PsA, UC | | |
| Xeljanz® XR (tofacitinib extended-release tablets) | Inhibition of JAK pathways | RA, PsA, UC | | |

* Not an all-inclusive list of indication (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; IV – Intravenous, IL – Interleukin; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; ^ Off-label use of Kineret in systemic JIA supported in guidelines; DMARDs – Disease-modifying antirheumatic drug.

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ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY:
ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។
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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.

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

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

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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).
XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).
CHÚ Ý: Nếu ban nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho ban. Goi 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).
ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ
1.800.940.5049 (TTY: 763.847.4013).
ማስታወሻ: የሚናንሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049
(መስጣት ለተሳናቸው: 763.847.4013 ).
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